

(19) World Intellectual Property
Organization
International Bureau



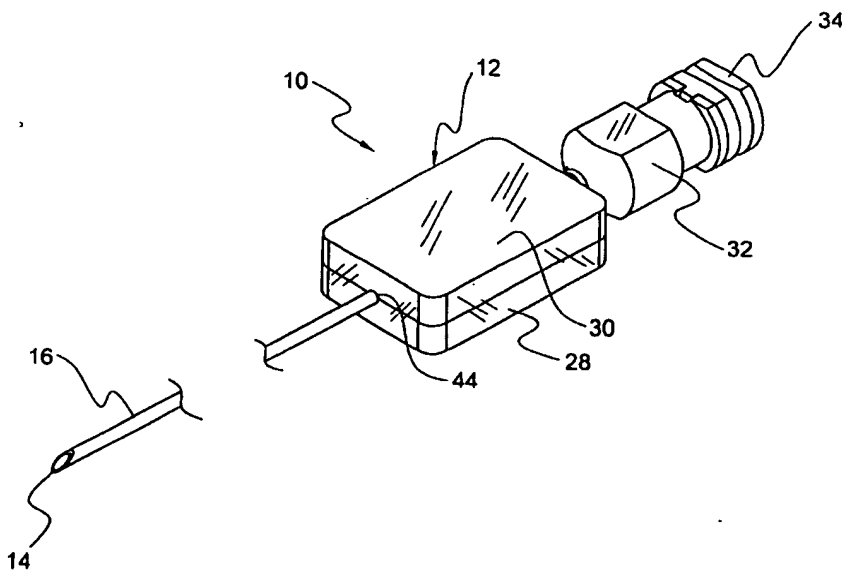
(43) International Publication Date
19 February 2004 (19.02.2004)

PCT

(10) International Publication Number
WO 2004/014464 A1

- (51) International Patent Classification⁷: **A61M 5/00**
- (21) International Application Number:
PCT/US2003/022093
- (22) International Filing Date: 14 July 2003 (14.07.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
10/202,201 23 July 2002 (23.07.2002) US
- (71) Applicant: **SPECIALIZED HEALTH PRODUCTS, INC.** [US/US]; Suite 200, 585 West 500 South, Bountiful, UT 84010-8199 (US).
- (72) Inventor: **FERGUSON, F., Mark**; Suite 200, 585 West 500 South, Bountiful, UT 84010-8199 (US).
- (74) Agent: **EVANS, Paul**; Suite 200, 585 West 500 South, Bountiful, UT 84101-8199 (US).
- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:**
— with international search report
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: SAFETY SHIELD FOR MEDICAL NEEDLES



(57) Abstract: A medical needle shield apparatus (10) is provided which is slidably movable along a medical needle (16) from a proximal position where a distal end of the needle is exposed, to a distal position where the shield (10) protects the distal end of the needle (16). The medical needle shield apparatus (10) includes a binding member (18) having an aperture through which the needle (16) passes. The binding member (18) also has binding surfaces (22) for binding to a medical needle (16). The shield apparatus also includes a retainer (24) integral with the binding member (18) and in communication with the needle (16) for temporarily retaining the binding surfaces (22) in a non-binding position relative to the needle (16). The shield apparatus (10) also includes a positioning member (26) for positioning the binding surfaces (22) to secure the shield (10) to the needle (16) when a portion of the retainer (36) in contact with the needle (16) is advanced past the distal end of the needle (16).

SAFETY SHIELD FOR MEDICAL NEEDLES

5 CROSS-REFERENCE TO RELATED APPLICATIONS

This patent application is a continuation-in-part of U.S. Utility Patent Application Serial No. 09/809,357, filed in the U.S. Patent and Trademark Office on March 15, 2001 by Ferguson et al., the entire contents of which being hereby incorporated by reference herein.

BACKGROUND

10 1. Technical Field

The present disclosure generally relates to safety shields for medical needles, and more particularly, to safety shields that protect a needle point of a medical needle.

2. Description of the Related Art

15 Problems associated with inadvertent needle sticks are well known in the art of blood sampling, percutaneous medication injection and other medical procedures involving use of medical needles. Significant attention has been focused on needle stick problems due to the contemporary sensitivity of exposure to AIDS, Hepatitis and other serious blood-borne pathogen exposures.

20 Procedures for removing a needle from a patient commonly require a technician to use one hand to place pressure at the wound site where the needle is being withdrawn, while removing the needle device with the other hand. It is also common practice for an attending technician to give higher priority to care for the wound than is given to disposal of a needle. In the case of typical needle devices without safety shields, such priority either requires the convenience of an available sharps container within reach or another means for safe disposal
25 without leaving the patient's side. Providing adequate care while following safety procedures is often compounded by the patient's physical condition and mental state, such as in burn units and psychiatric wards. Under such conditions, it is difficult to properly dispose of a used needle while caring for a patient.

30 The widespread knowledge and history associated with needle care and disposal problems have resulted in numerous devices for preventing accidental needle sticks. Problems of current

safety devices include difficulty of use and high cost due to their complexity and number of parts.

Other known devices employ sheaths that are spring activated, telescoping, pivoting, etc. These devices, however, may disadvantageously misfire or be cumbersome to activate. Further
5 drawbacks of current devices include high manufacturing cost due to complexity and the number of parts. Thus, these type prior art devices may not adequately and reliably shield medical needle apparatus to prevent hazardous exposure.

Consequently, there remains a need to provide a more satisfactory solution for needle safety devices by overcoming the disadvantages and drawbacks of the prior art. Therefore, it
10 would be desirable to provide a more adequate and reliable medical needle shield apparatus which employs a safety shield slidably movable along a medical needle to prevent hazardous exposure to a needle tip. Such a needle shield apparatus should be easily and reliably movable to shield a needle tip of a needle cannula.

SUMMARY

15 Accordingly, the present disclosure addresses a need for a medical needle shield apparatus which effectively and inexpensively protects a tip of a medical needle after use. The present disclosure resolves related disadvantages and drawbacks experienced in the art. More specifically, the apparatus and method of this invention constitute an important advance in the art of safety needle devices.

20 In one particular embodiment, a medical needle shield apparatus is provided in accordance with the principles of the present disclosure. The shield is slidably movable along a medical needle from a proximal position where a distal end of the needle is exposed, to a distal position where the shield protects the distal end of the needle. The medical needle shield apparatus includes a binding member having an aperture through which the needle passes. The
25 binding member also has binding surfaces for binding to a medical needle. The shield apparatus also includes a retainer integral with the binding member and in communication with the needle for temporarily retaining the binding surfaces in a non-binding position relative to the needle. The shield apparatus also includes a positioning member for positioning the binding surfaces to secure the shield to the needle when a portion of the retainer in contact with the needle is
30 advanced past the distal end of the needle and allows the retainer to release from the needle and move out of an axial path defined by the needle. The retainer may also be configured so that it does not move out of an axial path defined by the needle. A housing may be included for enclosing the shield apparatus.

In one particular embodiment, the shield apparatus includes a positioning member comprising a leaf spring integral to the binding member. Alternatively, the positioning member may comprise one or more friction elements disposed on the medical needle. In another particular embodiment, the positioning member comprises a unitary friction element disposed on the medical needle.

In another particular embodiment, the shield apparatus includes a retainer having a slot for permitting a guidewire to extend through the safety shield apparatus.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other features and advantages of the present invention will be more fully understood from the following detailed description of the illustrative embodiments, taken in conjunction with the accompanying drawings in which:

FIGURE 1 is a perspective view of a medical needle safety shield apparatus in a retracted position, in accordance with the principles of the present invention;

FIGURE 2 is a side view of the safety shield apparatus shown in FIGURE 1 with the top portion of the housing of the medical needle safety apparatus removed;

FIGURE 3 is a perspective view of the safety shield apparatus illustrated in FIGURE 1 with the components separated;

FIGURE 4 is a perspective view of a portion of the components of the safety shield apparatus shown in FIGURE 1;

FIGURE 5 is a perspective view of the safety shield apparatus illustrated in FIGURE 1 fully extended;

FIGURE 6 is a side view of the safety shield apparatus shown in FIGURE 5 with the top portion of the housing removed and showing a first blocking member of the housing urging the binding member into a binding orientation as it moves to toward the proximal end of the needle;

FIGURE 7 is a side view of the safety shield apparatus shown in FIGURE 5 with the top portion of the housing removed and showing a second blocking member of the housing urging the binding member into a binding orientation as it moves to toward the distal end of the needle;

FIGURE 8 is a perspective view of the safety shield apparatus illustrated in FIGURE 1 showing an alternate retainer embodiment, which includes a slot for permitting a guidewire to extend through the safety shield apparatus;

5 FIGURE 9 is a side view of the safety shield apparatus illustrated in FIGURE 1 with the top portion of the housing removed and showing an alternate binding member and retainer embodiment;

FIGURE 10 is a side view of the safety shield apparatus shown in FIGURE 5 with the top portion of the housing removed and showing a first blocking member of the housing urging the binding member into a binding orientation as it moves to toward the proximal end of the needle;

10 FIGURE 11 is a side view of the safety shield apparatus shown in FIGURE 5 with the top portion of the housing removed and showing a second blocking member of the housing urging the binding member into a binding orientation as it moves to toward the distal end of the needle;

FIGURE 12 is a perspective view of the safety shield apparatus illustrated in FIGURE 9 with the components separated;

15 FIGURE 13 is a perspective view of a portion of the components of the safety shield apparatus shown in FIGURE 9;

FIGURE 14 is a side view of the safety shield apparatus illustrated in FIGURE 1 with the top portion of the housing removed and showing an alternate binding member and positioning member embodiment;

20 FIGURE 15 is a side view of the safety shield apparatus shown in FIGURE 14 with the top portion of the housing removed and showing a first blocking member of the housing urging the binding member into a binding orientation as it moves to toward the proximal end of the needle;

25 FIGURE 16 is a side view of the safety shield apparatus shown in FIGURE 14 with the top portion of the housing removed and showing a second blocking member of the housing urging the binding member into a binding orientation as it moves to toward the distal end of the needle;

FIGURE 17 is a perspective view of the safety shield apparatus illustrated in FIGURE 14 with the components separated;

FIGURE 18 is a side view of the safety shield apparatus illustrated in FIGURE 1 showing an alternate binding member and positioning member embodiment;

FIGURE 19 is a side view of the safety shield apparatus shown in FIGURE 18 with the top portion of the housing removed and showing a first blocking member of the housing urging the binding member into a binding orientation as it moves to toward the proximal end of the needle;

FIGURE 20 is a side view of the safety shield apparatus shown in FIGURE 18 with the top portion of the housing removed and showing a second blocking member of the housing urging the binding member into a binding orientation as it moves to toward the distal end of the needle;

FIGURE 21A is a perspective view of the safety shield apparatus illustrated in FIGURE 18 with the components separated;

FIGURE 21B is a perspective view of the safety shield apparatus illustrated in FIGURE 18 with the components separated and showing an alternate binding member embodiment;

FIGURE 22 is a perspective view of the safety shield apparatus illustrated in FIGURES 14 and 18 showing an alternate retainer embodiment, which includes a slot for permitting a guidewire to extend through the safety shield apparatus;

FIGURE 23 is a perspective view of the safety shield apparatus illustrated in FIGURE 1 with the top portion of the housing removed and showing an alternate binding member and positioning member embodiment;

FIGURE 24 is a side view of the safety shield apparatus shown in FIGURE 23 with the top portion of the housing removed and showing a first blocking member of the housing urging the binding member into a binding orientation as it moves to toward the proximal end of the needle;

FIGURE 25 is a side view of the safety shield apparatus shown in FIGURE 23 with the top portion of the housing removed and showing a second blocking member of the housing urging the binding member into a binding orientation as it moves to toward the distal end of the needle;

FIGURE 26 is a perspective view of the safety shield apparatus illustrated in FIGURE 23 with the components separated;

FIGURE 27 is a perspective view of the safety shield apparatus illustrated in FIGURE 23 showing an alternate retainer embodiment, which includes a slot for permitting a guidewire to extend through the safety shield apparatus;

FIGURE 28 is a side view of the safety shield apparatus shown in FIGURE 23 with the top portion of the housing removed and showing the alternate retainer embodiment illustrated in FIGURE 27 providing for a guidewire to pass through;

FIGURE 29 is a perspective view of a safety shield apparatus having a second shield for protecting a distal end of a stylet passed through a bore of the needle; and

FIGURE 30 is a perspective view of the safety shield apparatus shown in FIGURE 29 with the first shield protecting the distal end of a needle and the second shield protecting the distal end of a stylet after use.

DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

The exemplary embodiments of the medical needle shield apparatus and methods of operation disclosed are discussed in terms of medical needles for infusion of intravenous fluids, medication infusion or fluid collection, and more particularly, in terms of needle shield apparatus employed with a needle cannula that prevent hazardous exposure to the needle tip, including, for example, inadvertent needle sticks. It is envisioned that the present disclosure, however, finds application to a wide variety of cannula needles and devices for the infusion of preventive medications, medicaments, therapeutics, etc. to a subject. It is also envisioned that the present disclosure may be employed for collection of body fluids including those employed during procedures relating to phlebotomy, digestive, intestinal, urinary, veterinary, etc. It is contemplated that the medical needle shield apparatus may be utilized with other medical needle applications including, but not limited to, fluid infusion, fluid collection, catheters, catheter introducers, guidewire introducers, spinal and epidural, biopsy, aphaeresis, dialysis, blood donor, Veress needles, Huber needles, etc.

In the discussion that follows, the term "proximal" refers to a portion of a structure that is closer to a clinician, and the term "distal" refers to a portion that is further from the clinician. As used herein, the term "subject" refers to a patient that receives infusions or has blood and/or fluid collected therefrom using the medical needle shield apparatus. According to the present disclosure, the term "clinician" refers to an individual administering an infusion, performing fluid collection, installing or removing a needle cannula from a medical needle shield apparatus and may include support personnel.

The following discussion includes a description of the medical needle shield apparatus, followed by a description of the method of operating the medical needle shield apparatus in accordance with the present disclosure. Reference will now be made in detail to the exemplary embodiments of the disclosure, which are illustrated in the accompanying figures.

5 Turning now to the figures, wherein like components are designated by like reference numerals throughout the several views. Referring initially to FIGURES 1-7, there is illustrated a safety shield assembly 10, constructed in accordance with the principals of the present disclosure, including a needle, such as, for example, medical needle 16 having a distal end 14. Safety shield assembly 10 is advantageously configured to prevent hazardous exposure to the distal end 14 of a
10 needle cannula 16 by providing an adequate and reliable medical needle shield apparatus for a medical needle 16 which shields the distal end 14 of a needle 16, as will be discussed below.

 Safety shield assembly 10 may include a housing 12 having a first section 28 and second section 30 for ease of assembly. Housing 12 includes openings 44 sized to allow the needle 16 to pass through. Safety shield 10 is disposed on a needle 16 of a medical needle
15 device to facilitate safe disposal of a medical needle device. FIGURE 1 illustrates safety shield assembly 10 disposed near the hub 32 of on a needle having a stylet 34.

 Safety shield 10 is slidably movable along a needle 16 from a proximal position where a distal end 14 of the needle 16 is exposed, to a distal position where the safety shield 10 protects the distal end 14 of the needle 16. Safety shield 10 includes a binding member 18
20 having an aperture 22 through which the needle 16 passes. The binding member 18 also has binding surfaces 22 for binding to a medical needle 16. The safety shield 10 also includes a retainer 24 integral with the binding member 18 and in communication with the needle 16 for temporarily retaining the binding surfaces 22 in a non-binding position relative to the needle 16. The positioning member 26 illustrated in FIGURES 1-7 comprises a leaf spring integral
25 to the binding member 18. The safety shield 10 also includes a positioning member 26 for positioning the binding surfaces 22 in a binding orientation to secure the safety shield 10 to the needle 16 when a portion 36 of the retainer 24 in contact with the needle 16 is advanced past the distal end 14 of the needle 16 and allows the retainer 24 to release from the needle 16 and move out of an axial path defined by the needle 16. The retainer 24 may also be
30 configured such that it does not move out of an axial path defined by the needle 16. The housing 12 may further include needle supports 38 for guiding the needle through the safety shield 10. A first blocking member 40 and second blocking member 42 urge the binding member 18 into a binding orientation. The first and second blocking members 40 and 42 may also be utilized to retain the binding member 18 to the housing 12. It is contemplated

that housing 12 may also include features for retaining the binding member 18 to the housing 12. The binding member 18 makes contact with the housing 12 at first blocking member 40 and second blocking member 42. First blocking member 40 and second blocking member 42 are placed on opposite sides of, and at distances perpendicular to, the long axis of needle 16.

5 The binding member 18 is generally a stiff plate. The aperture 20 may be round, rectangular, or of any shape having binding surfaces 22 on opposing sides of the aperture 20. The aperture 20 need not be closed on all sides, such as for example "U" shaped wherein the aperture 20 may be open to one or more edges of the binding member 18. The aperture 20 is sized to allow the needle 16 to slide within the aperture 20 when the binding member 18 is
10 positioned at one angle relative to the long axis of the needle 16 (generally close to perpendicular), and also sized so as to bring the binding surfaces 22 of the aperture 20 into binding contact with the needle 16 when the binding member 18 is positioned at a different angle relative to the long axis of the needle 16. This angle is referred to as the binding orientation.

15 As the safety shield 10 is urged in the proximal direction, first blocking member 40 urges the binding member 18 in a direction tending toward the binding orientation (see FIGURE 6). As the safety shield 10 is urged in the distal direction, second blocking member 42 urges the binding member 18 in a direction tending toward the binding orientation (see FIGURE 7).

20 The portion 36 on the retainer 24 in communication with the needle 16 is positioned such that when it is in contact with the needle 16, the binding member 18 is in a sliding orientation relative to the needle 16. Portion 36, by virtue of its contact with needle 16, maintains the sliding orientation of the binding member 18 by opposing the force provided by the positioning member 26, which would otherwise urge the binding member 18 into the
25 binding position. As the safety shield 10 is moved towards the distal end 14 of the needle 16 and positioned such that portion 36 is distal of the distal end 14 of the needle 16, the binding member 18 is free to move into the binding orientation as urged by the positioning member 26. In this particular embodiment, portion 36 is a portion of a circular hole, but other surfaces may be utilized to accomplish the same function.

30 The positioning member 26 extends from the binding member 18, and is configured such that when the binding member 18 is in the sliding orientation, the positioning member 26 is slideably in contact with, and compressed against, the needle 16 in such a way as to provide a force tending to urge the binding member 18 into the binding orientation, but selectably opposed by portion 36 as described above. The binding member 18 may be

unitary with a resilient positioning member 26. The positioning member 26 may take other resilient shapes such as a coil or accordion. Other portions of the binding member 18 may be more stiff, which may be accomplished by varying the geometry such as the thickness, width, etc.

5 Binding of the binding member 18 to the needle 16 is a function of the friction force generated between the aperture binding surfaces 22 and the needle 16. Sharp edges are advantageous, but not required. The friction force generated is a function of the aperture 20 dimension, the needle 16 diameter, the binding member 18 thickness, the distance between the first and second blocking members 40 and 42 to the centerline of the needle 16, and the
10 coefficient of friction between the aperture 20 and the needle 16. One skilled in the art may easily derive an equation demonstrating that these key elements may be arranged in such a way as to ensure that the friction force generated will always be sufficient to bind the binding member 18 to the needle 18 for any force applied to the safety shield 10 up to the point of material failure of at least one of the elements.

15 Safety shield 10 can be fabricated from a material suitable for medical applications, such as, for example, polymeric or metals, such as stainless steel, depending on the particular medical application and/or preference of a clinician. Semi-rigid and rigid polymeric are contemplated for fabrication, as well as resilient materials, such as molded medical grade polypropylene. However, one skilled in the art will realize that other materials
20 and fabrication methods suitable for assembly and manufacture, in accordance with the present disclosure, also would be appropriate.

Safety shield 10 may also be adapted for use with a medical needle device having a guidewire introducer, such as a Seldinger needle. An alternate embodiment of retainer 24' is shown in FIGURE 8, which includes a slot 46 for permitting a guidewire, stylet, or other
25 element passed through the bore of needle 16, to extend through the safety shield 10. Similar to the binding member 18 shown in FIGURES 1-7, the binding member 18' includes an aperture 22' through which the needle 16 passes. The binding member 18' also has binding surfaces 22' for binding to a medical needle 16. A retainer 24' integral with the binding member 18' communicates with the needle 16 for temporarily retaining the binding surfaces
30 22' in a non-binding position relative to the needle 16. The positioning member 26' illustrated in FIGURE 8 comprises a leaf spring integral to the binding member 18'. Positioning member 26' positions the binding surfaces 22' to secure the safety shield 10' to the needle 16 when a portion 36' of the retainer 24' in contact with the needle 16 is advanced past the distal end 14 of the needle 16 and allows the retainer 24' to release from the needle 16 and
35 move out of an axial path defined by the needle 16.

An alternate embodiment of retainer 24" is illustrated in FIGURES 9-13, wherein the portion 36" on retainer 24" in communication with needle 16 comprises a planar surface in contact with the needle 16. Safety shield 10' is slidably movable along a needle 16 from a proximal position where a distal end 14 of the needle 16 is exposed, to a distal position where the safety shield 10' protects the distal end 14 of the needle 16. Safety shield 10' includes a binding member 18" having an aperture 22" through which the needle 16 passes. The binding member 18" also has binding surfaces 22" for binding to a medical needle 16. The safety shield 10' also includes a retainer 24" integral with the binding member 18" and in communication with the needle 16 for temporarily retaining the binding surfaces 22" in a non-binding position relative to the needle 16. The positioning member 26" illustrated in FIGURES 9-13 comprises a leaf spring integral to the binding member 18". The safety shield 10' also includes a positioning member 26" for positioning the binding surfaces 22" to secure the safety shield 10' to the needle 16 when a portion 36" of the retainer 24" in contact with the needle 16 is advanced past the distal end 14 of the needle 16 and allows the retainer 24" to release from the needle 16 and move out of an axial path defined by the needle 16. The housing 12 may further include needle supports 38 for guiding the needle 16 through the safety shield 10'. A first blocking member 40 and second blocking member 42 may be provided to urge the binding member 18" into a binding orientation. First blocking member 40 urges the binding member 18" into a binding orientation as it is moved towards the proximal end of needle 16, as shown in FIGURE 10. Second blocking member 42 urges the binding member 18" into a binding orientation as it is moved towards the distal end 14 of needle 16, as shown in FIGURE 11.

An alternate embodiment of positioning member is illustrated in FIGURES 14-17, wherein the positioning member comprises friction elements 48 having a sliding friction fit on the needle 16. Safety shield 10" is slidably movable along a needle 16 from a proximal position where a distal end 14 of the needle 16 is exposed, to a distal position where the safety shield 10" protects the distal end 14 of the needle 16. Safety shield 10" includes a binding member 18"" having an aperture 22"" through which the needle 16 passes. The binding member 18"" also has binding surfaces 22"" for binding to a medical needle 16. The safety shield 10" also includes a retainer 24"" integral with the binding member 18"" and in communication with the needle 16 for temporarily retaining the binding surfaces 22"" in a non-binding position relative to the needle 16. The combination of the force generated by the friction elements 48, the force input from the first blocking member 40 or second blocking member 42 upon interface with binding member 18"", and the lever or moment arm formed by the binding member 18"" forms a couple which provides a force tending to urge the

binding member 18''' into binding orientation. The friction elements 48 thus position the binding surfaces 22''' to secure the safety shield 10'' to the needle 16 when a portion 36''' of the retainer 24''' in contact with the needle 16 is advanced past the distal end 14 of the needle 16 and allows the retainer 24''' to release from the needle 16. The housing 12 may further include needle supports 38 for guiding the needle 16 through the safety shield 10''. A first blocking member 40 and second blocking member 42 may be provided to urge the binding member 18''' into binding orientation. First blocking member 40 urges binding member 18''' into a binding orientation as it is moved towards the proximal end of needle 16, as shown in FIGURE 15. Second blocking member 42 urges binding member 18''' into a binding orientation as it is moved towards the distal end 14 of needle 16, as shown in FIGURE 16.

The friction elements 48, as described above, may be joined to create a unitary friction element 50 as shown in FIGURES 18-21. Safety shield 10''' is slidably movable along a needle 16 from a proximal position where a distal end 14 of the needle 16 is exposed, to a distal position where the safety shield 10''' protects the distal end 14 of the needle 16. Safety shield 10''' includes a binding member 18''' having an aperture 22''' through which the needle 16 passes. The binding member 18''' also has binding surfaces 22''' for binding to a medical needle 16. The safety shield 10''' also includes a retainer 24''' integral with the binding member 18''' and in communication with the needle 16 for temporarily retaining the binding surfaces 22''' in a non-binding position relative to the needle 16. The combination of the force generated by the first surface 52 and second surface 54 of unitary friction elements 50, the force input from the first blocking member 40 or second blocking member 42 upon interface with binding member 18'', and the lever or moment arm formed by the binding member 18''' forms a couple which provides a force tending to urge the binding member 18''' into binding orientation. It is also contemplated that other geometries may be utilized which accomplish the same function as first surface 52 and second surface 54. The unitary friction element 50 thus positions the binding surfaces 22''' to secure the safety shield 10''' to the needle 16 when a portion 36''' of the retainer 24''' in contact with the needle 16 is advanced past the distal end 14 of the needle 16 and allows the retainer 24''' to release from the needle 16. The housing 12 may further include needle supports 38 for guiding the needle 16 through the safety shield 10''. A first blocking member 40 and second blocking member 42 may be provided to urge the binding member 18''' into binding orientation. First blocking member 40 urges the binding member 18''' into a binding orientation as it is moved towards the proximal end of needle 16, as shown in FIGURE 19. Second blocking member 42 urges the binding member 18''' into a binding orientation as it is moved towards the distal end 14 of needle 16, as shown in FIGURE 20.

The binding member 18''' and portion 36''' on retainer 24''' may include "U" shaped apertures 19 and 37 respectively, as well as "U" shaped openings 53 and 55 on first surface 52 and second surface 54 respectively, to provide side installation of the needle 16 during assembly of the safety shield 10'''.

5 Safety shields 10'' and 10''' may also be adapted for use with a medical needle device having a guidewire introducer, such as a Seldinger needle. An alternate embodiment of retainer 24''' is shown in FIGURE 22, which includes a slot 46' for permitting a guidewire to extend through the safety shield 10'' or 10'''. Similar to the binding members 18'' and 18''' shown in FIGURES 14-21, the binding member 18''' includes an aperture 22''' through which
10 the needle 16 passes. The binding member 18''' also has binding surfaces 22''' for binding to a medical needle 16. A retainer 24''' integral with the binding member 18''' communicates with the needle 16 for temporarily retaining the binding surfaces 22''' in a non-binding position relative to the needle 16.

 The friction elements 62 may also be integral to the binding member 64 as shown in
15 FIGURES 23-27. Other friction element 62 configurations are contemplated which accomplish the same function of creating drag on the needle in such a way as to selectably promote binding. Safety shield 60 is slidably movable along a needle 16 from a proximal position where a distal end 14 of the needle 16 is exposed, to a distal position where the safety shield 60 protects the distal end 14 of the needle 16. Safety shield 60 includes a
20 binding member 64 having an aperture 66 through which the needle 16 passes. The binding member 64 also has binding surfaces 68 for binding to a medical needle 16. The safety shield 60 also includes a retainer 70 integral with the binding member 64 and in communication with the needle 16 for temporarily retaining the binding surfaces 68 in a non-binding position relative to the needle 16. The combination of the force generated by the friction elements 62,
25 the force input from the first blocking member 40 or second blocking member 42 upon interface with binding member 64, and the lever or moment arm formed by the binding member 64 forms a couple which provides a force tending to urge the binding member 64 into a binding orientation. The friction elements 62 thus position the binding surfaces 68 to secure the safety shield 60 to the needle 16 when a portion 72 of the retainer 70 in contact
30 with the needle 16 is advanced past the distal end 14 of the needle 16 and allows the retainer 70 to release from the needle 16. The housing 12 may further include needle supports 38 for guiding the needle 16 through the safety shield 60. A first blocking member 40 and second blocking member 42 may be provided to urge the binding member 64 into a binding orientation. First blocking member 40 urges the binding member 64 into a binding
35 orientation as it is moved towards the proximal end of needle 16, as shown in FIGURE 24.

Second blocking member 42 urges the binding member 64 into a binding orientation and retains housing 12 to the safety shield 60 as it is moved towards the distal end 14 of needle 16, as shown in FIGURE 25.

5 Safety shield 60 may also be adapted for use with a medical needle device having a guidewire 76, as shown in FIGURE 28. An alternate embodiment of retainer 70 is shown in FIGURES 27 and 28, which includes a slot 46" for permitting a guidewire to extend through the safety shield 60. Similar to the binding member 64 shown in FIGURES 23-26, the binding member 64' includes an aperture 66' through which the needle 16 passes. The binding member 64' also has binding surfaces 68' for binding to a medical needle 16. A
10 retainer 70' integral with the binding member 64' communicates with the needle 16 for temporarily retaining the binding surfaces 68' in a non-binding position relative to the needle 16.

It is contemplated that the present invention may include multiple safety shields for protecting the needle 16 and a stylet 84 or other element passed through a bore of the needle 16.
15 FIGURE 29 is a perspective view of a safety shield apparatus having a first safety shield assembly 80 and a second safety shield assembly 82 for protecting a distal end 86 of a stylet 84 passed through a bore of the needle 16. FIGURE 30 is a perspective view of the first and second safety shield assemblies 80 and 82, respectively, after actuation protecting the distal end 14 of a needle 16 and the distal end 86 of a stylet 84 after use. First and second safety shields 80 and 82
20 illustrated in FIGURE 30 are similar to safety shield assembly 60 shown in FIGURE 28. However, any of the above described safety shield assemblies may be utilized.

The invention of the present disclosure may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The present embodiments are therefore to be considered in all respects as illustrative and not restrictive,
25 the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

WHAT IS CLAIMED IS:

1. A medical needle shield apparatus comprising:
a shield slidably movable along a medical needle from a proximal position where a distal end
5 of the needle is exposed, to a distal position where the shield protects the distal end of the
needle, said shield comprising:
a binding member having an aperture through which the needle passes, said aperture having
binding surfaces;
a retainer integral with the binding member and in communication with the
10 needle for temporarily retaining the binding surfaces in a non-binding position relative to the
needle; and
a positioning member for positioning the binding surfaces to secure the shield
to the needle when a portion of the retainer in contact with the needle is advanced past the
distal end of the needle and allows the retainer to release from the needle and move out of an
15 axial path defined by the needle.
2. A medical needle shield apparatus as recited in claim 1, further comprising a
housing for enclosing the shield, wherein the housing includes openings for the needle to pass
through.
20
3. A medical needle shield apparatus as recited in claim 2, wherein the housing
further comprises first and second blocking members for urging the binding member into a
binding orientation.
- 25 4. A medical needle shield apparatus as recited in claim 1, wherein the
positioning member comprises a leaf spring integral to the binding member.
5. A medical needle shield apparatus as recited in claim 1, wherein the
positioning member comprises a resilient portion integral to the binding member.
30
6. A medical needle shield apparatus as recited in claim 1, wherein the
positioning member comprises one or more friction elements disposed on the medical needle.
7. A medical needle shield apparatus as recited in claim 1, wherein the one or
35 more friction elements are integral to the binding member.

8. A medical needle shield apparatus as recited in claim 1, wherein the positioning member comprises a unitary friction element disposed on the medical needle.

9. A medical needle shield apparatus as recited in claim 8, wherein the unitary friction element includes first and second surfaces for canting the binding member and the binding member aperture is disposed between the first and second surfaces.

10. A medical needle shield apparatus as recited in claim 1, wherein the portion on the retainer in contact with the needle further includes a slot extending therefrom.

10

11. A medical needle shield apparatus as recited in claim 1, further comprising a second shield for protecting a distal end of a stylet or other element passed through a bore of the needle.

12. A medical needle shield apparatus as recited in claim 1, further comprising a housing for enclosing the shield, wherein the housing includes openings for the needle to pass through.

15

13. A medical needle shield apparatus as recited in claim 12, wherein the housing further comprises first and second blocking members for urging the binding member into a binding orientation.

20

14. A medical needle shield apparatus as recited in claim 1, wherein the positioning member comprises a leaf spring integral to the binding member.

25

15. A medical needle shield apparatus as recited in claim 1, wherein the positioning member comprises one or more friction elements disposed on the medical needle.

16. A medical needle shield apparatus as recited in claim 15, wherein the one or more friction elements are integral to the binding member.

30

17. A medical needle shield apparatus as recited in claim 1, wherein the positioning member comprises a unitary friction element disposed on the medical needle.

18. A medical needle shield apparatus as recited in claim 17, wherein the unitary friction element includes first and second surfaces for canting the binding member and the binding member aperture is disposed between the first and second surfaces.

5 19. A medical needle shield apparatus as recited in claim 1, wherein the portion on the retainer in contact with the needle further includes a slot extending therefrom.

20. A medical needle shield apparatus as recited in claim 1, further comprising a second shield for protecting a distal end of a stylet or other element passed through a bore of
10 the needle.

21. A medical needle shield apparatus as recited in claim 1, further comprising a leaf spring integral to the binding member for positioning the binding surfaces to secure the shield to the needle when a portion of the retainer in contact with the needle is advanced past
15 the distal end of the needle and allows the retainer to release from the needle and move out of an axial path defined by the needle.

22. A medical needle shield apparatus as recited in claim 1, further comprising one or more friction elements disposed on the medical needle for positioning the binding
20 surfaces to secure the shield to the needle when a portion of the retainer in contact with the needle is advanced past the distal end of the needle and allows the retainer to release from the needle.

23. A medical needle shield apparatus as recited in claim 1, further comprising a
25 unitary friction element disposed on the needle and having first and second surfaces disposed fore and aft of the binding member aperture for canting the binding member and positioning the binding surfaces to secure the shield to the needle when a portion of the retainer in contact with the needle is advanced past the distal end of the needle and allows the retainer to release from the needle.

30 24. A medical needle shield apparatus as recited in claim 1, further comprising one or more friction elements integral with the binding member and disposed on the medical needle for positioning the binding surfaces to secure the shield to the needle when a portion of the retainer in contact with the needle is advanced past the distal end of the needle and
35 allows the retainer to release from the needle.

1/31

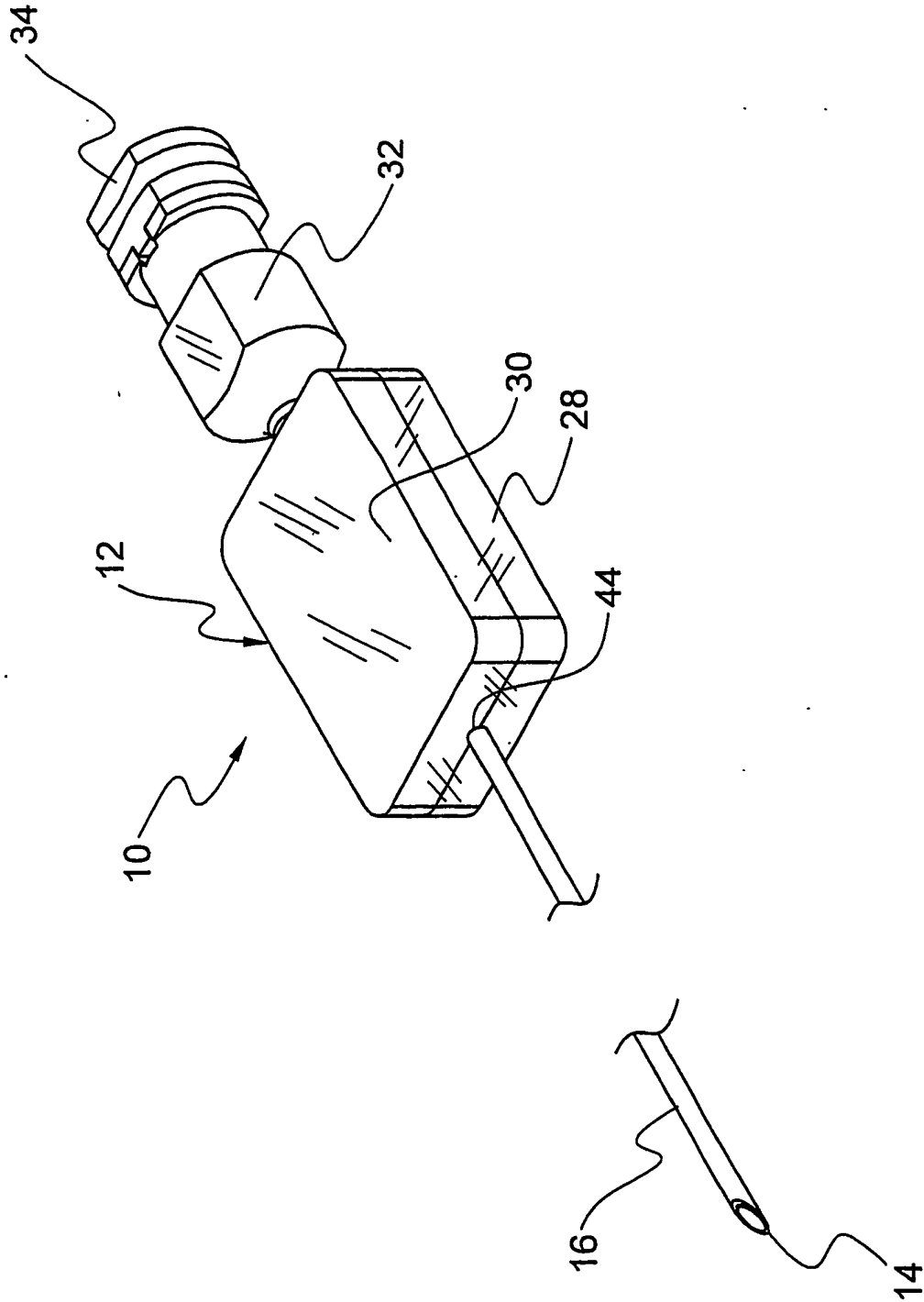


FIGURE 1

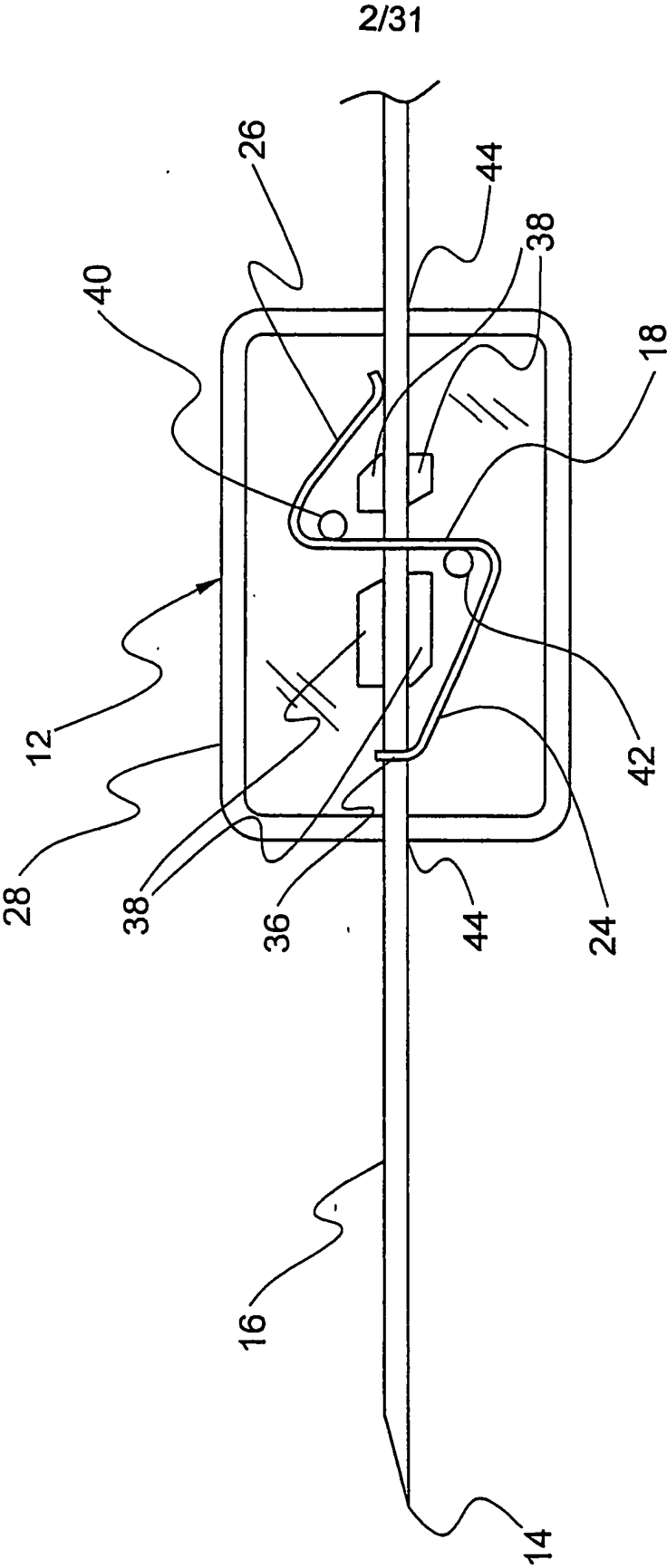


FIGURE 2

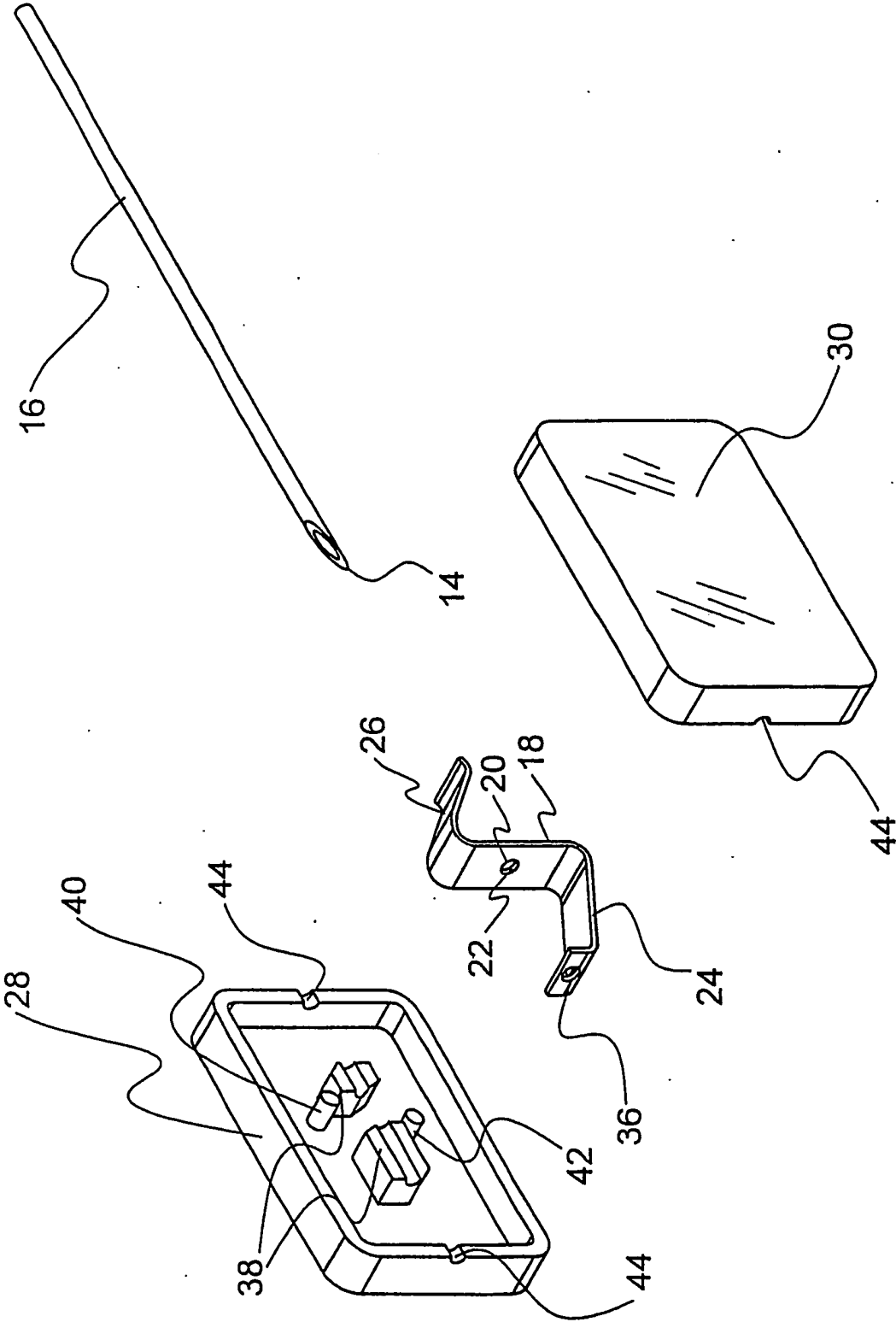


FIGURE 3

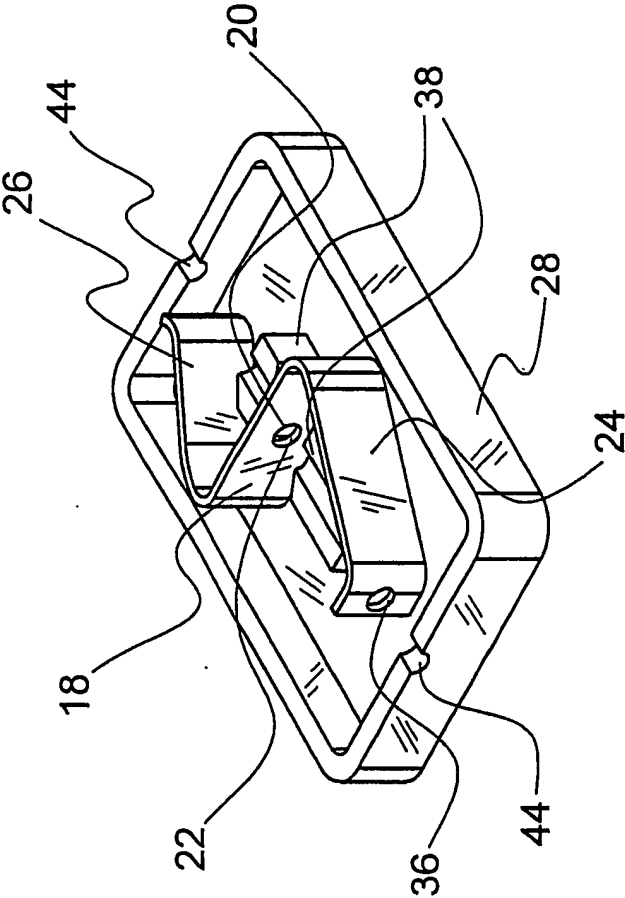


FIGURE 4

5/31

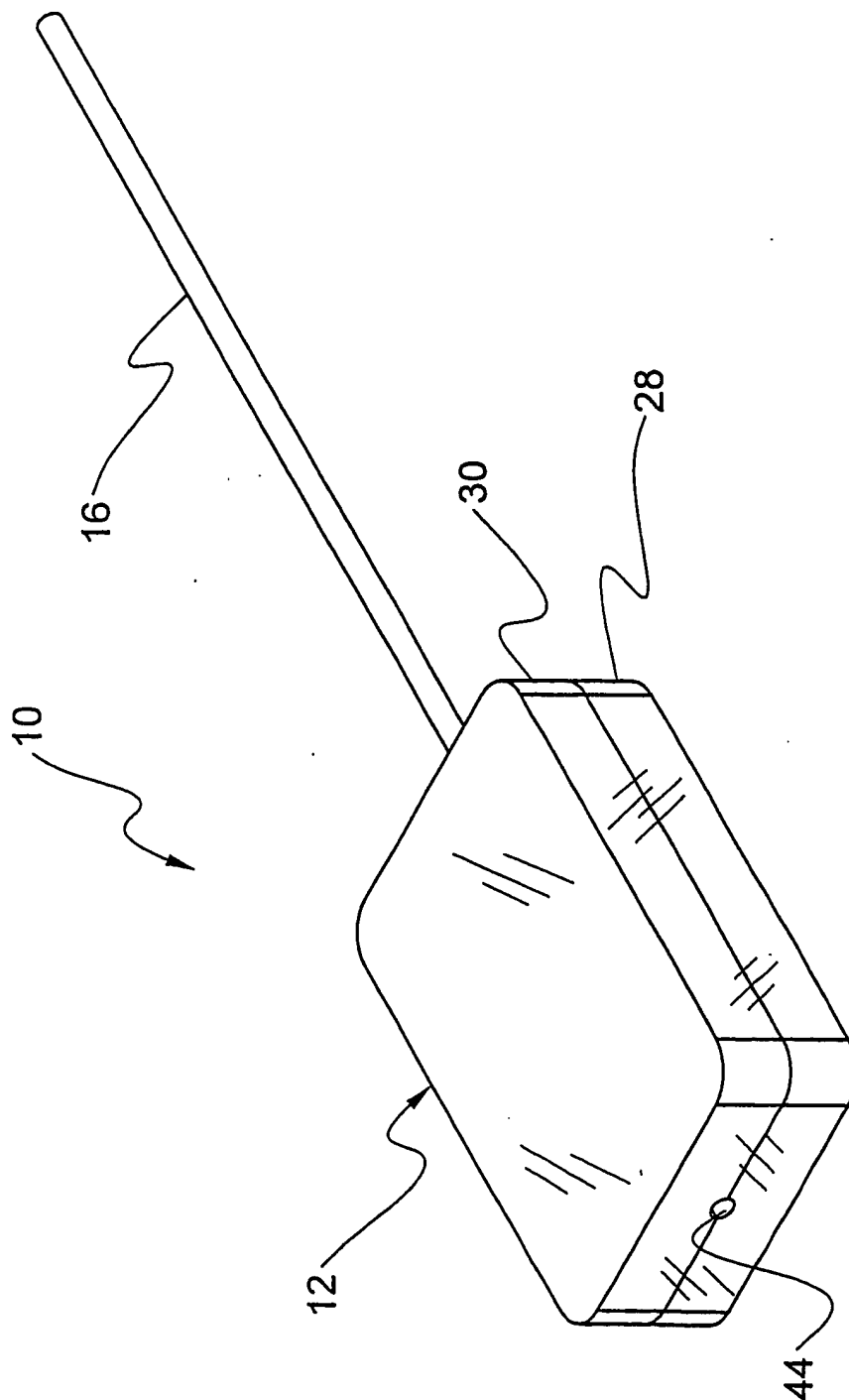


FIGURE 5

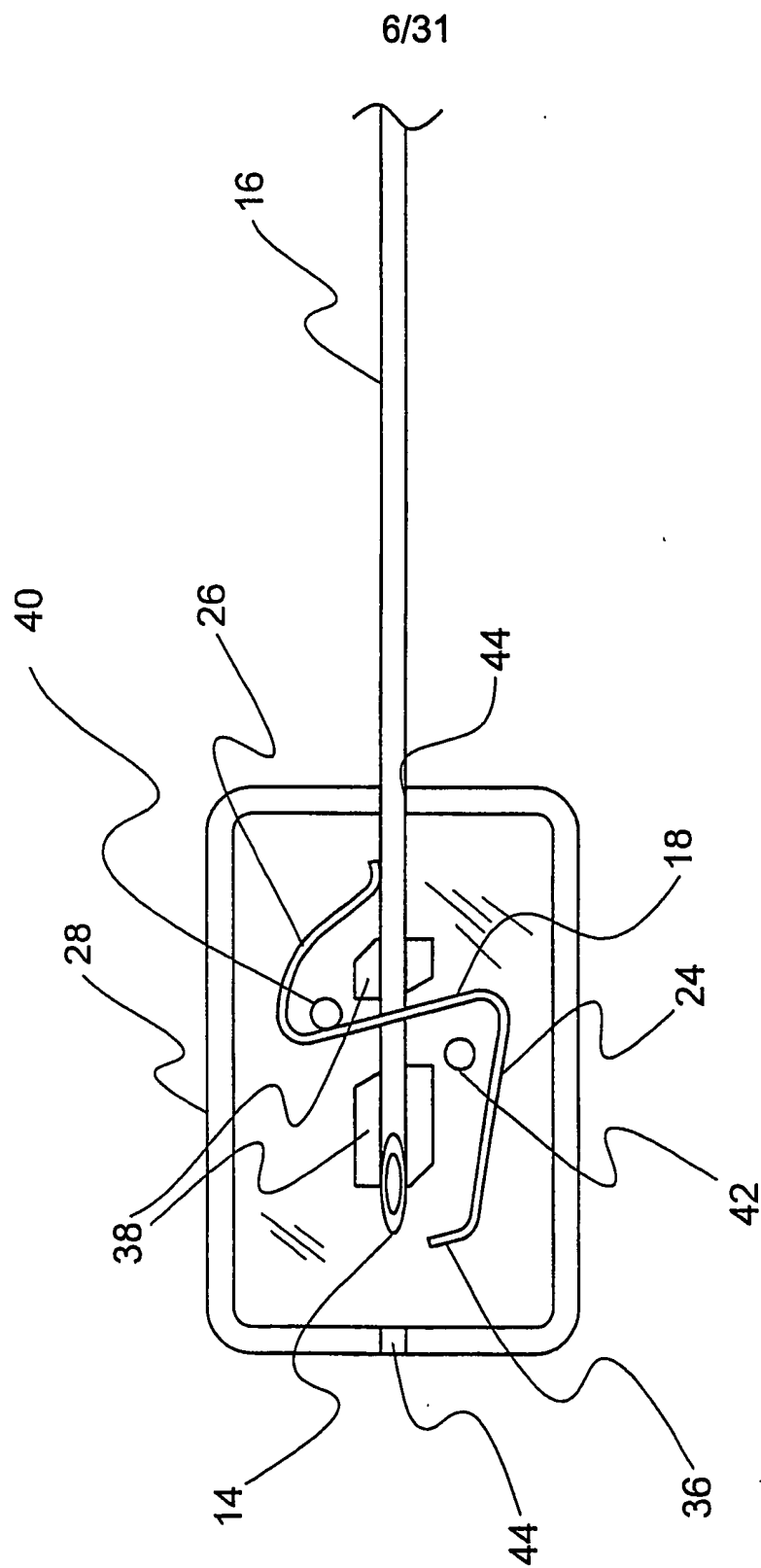


FIGURE 6

7/31

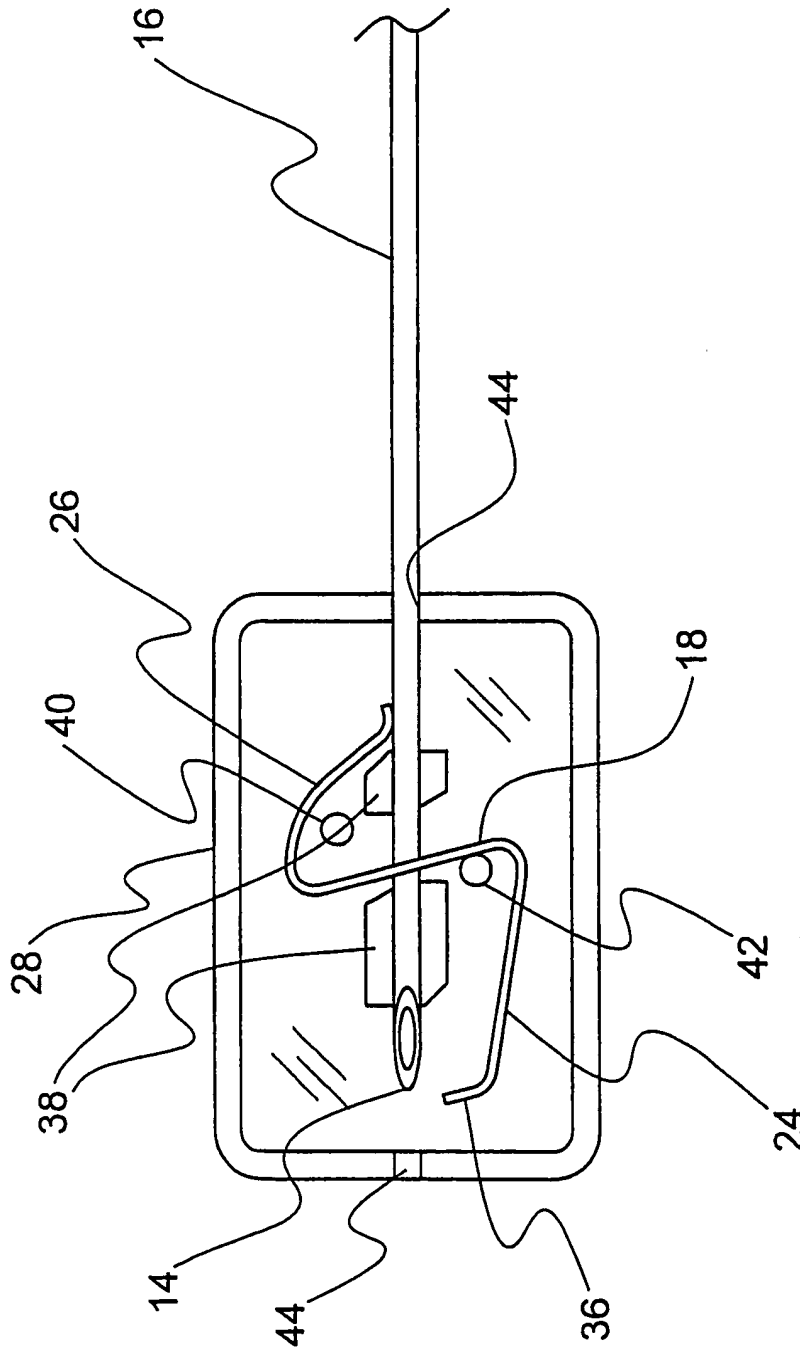


FIGURE 7

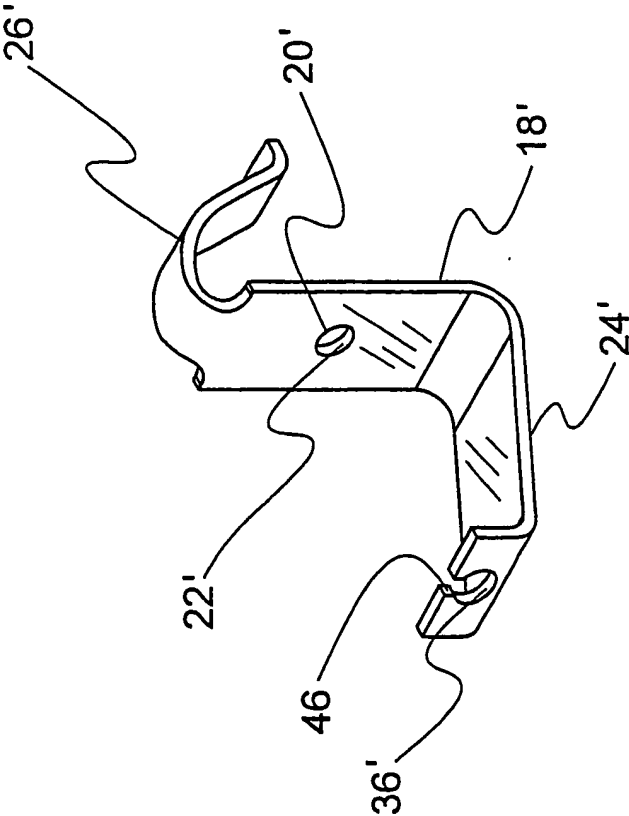


FIGURE 8

9/31

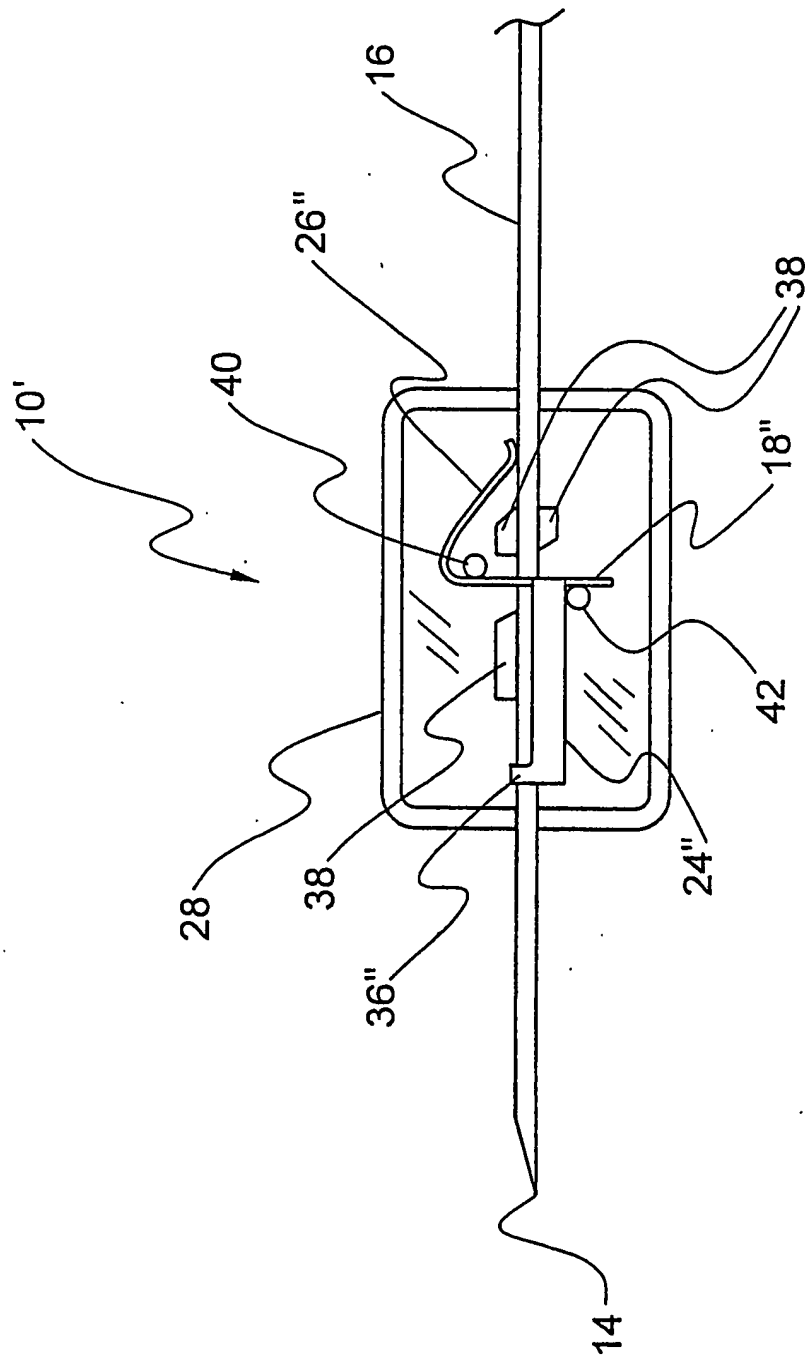


FIGURE 9

10/31

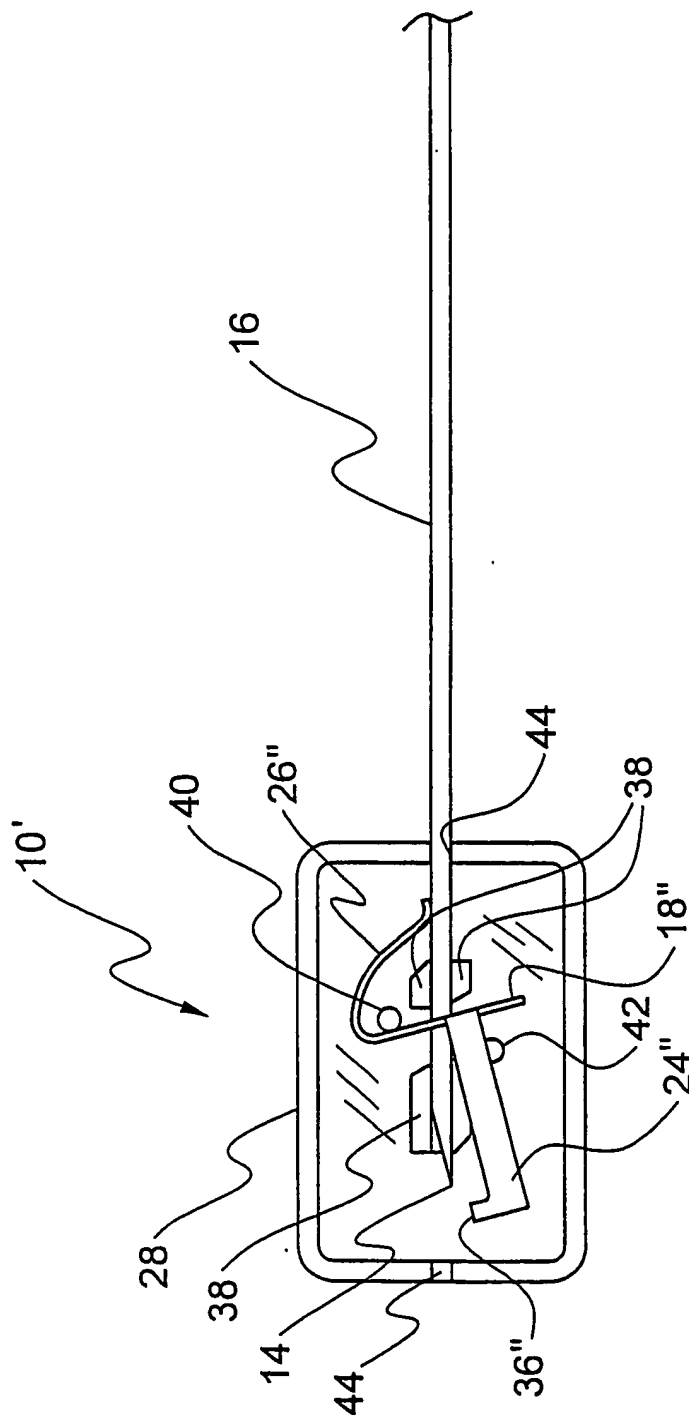


FIGURE 10

11/31

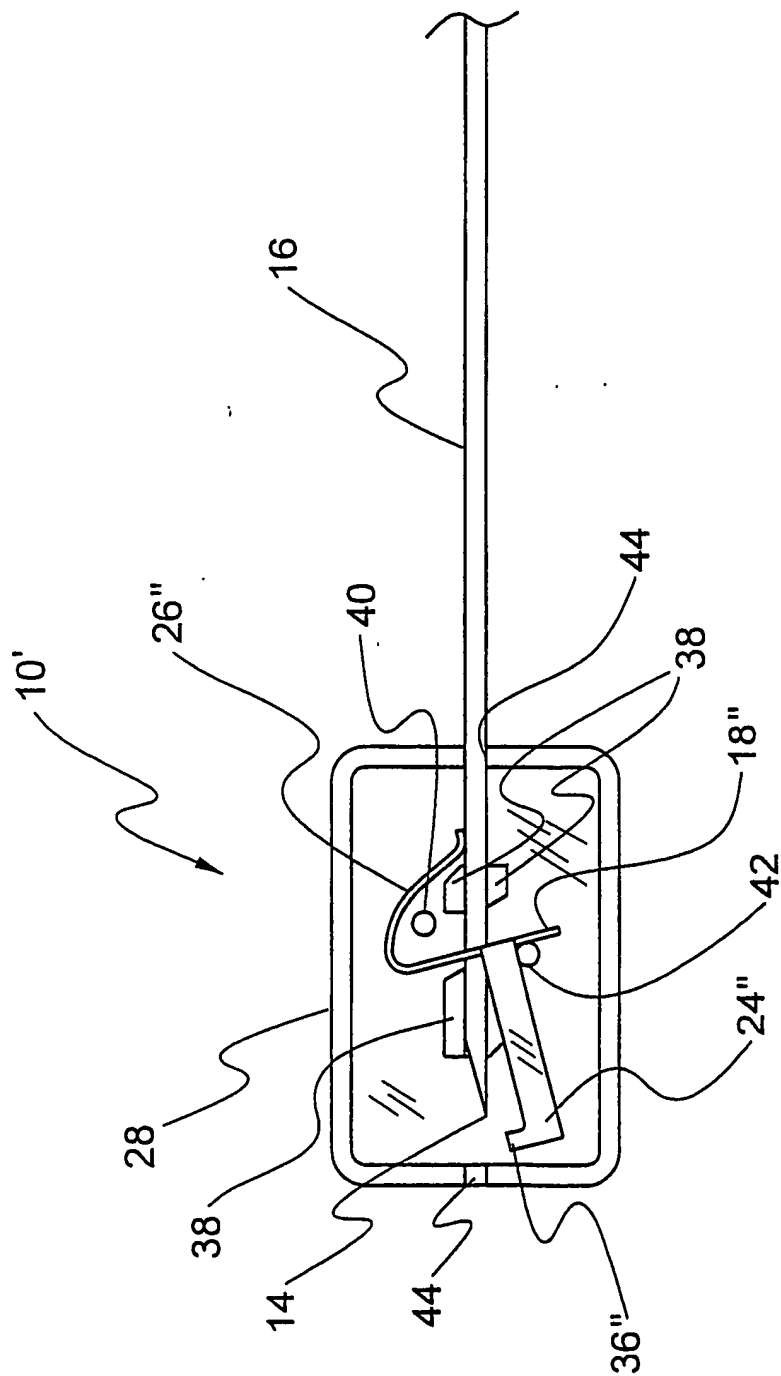


FIGURE 11

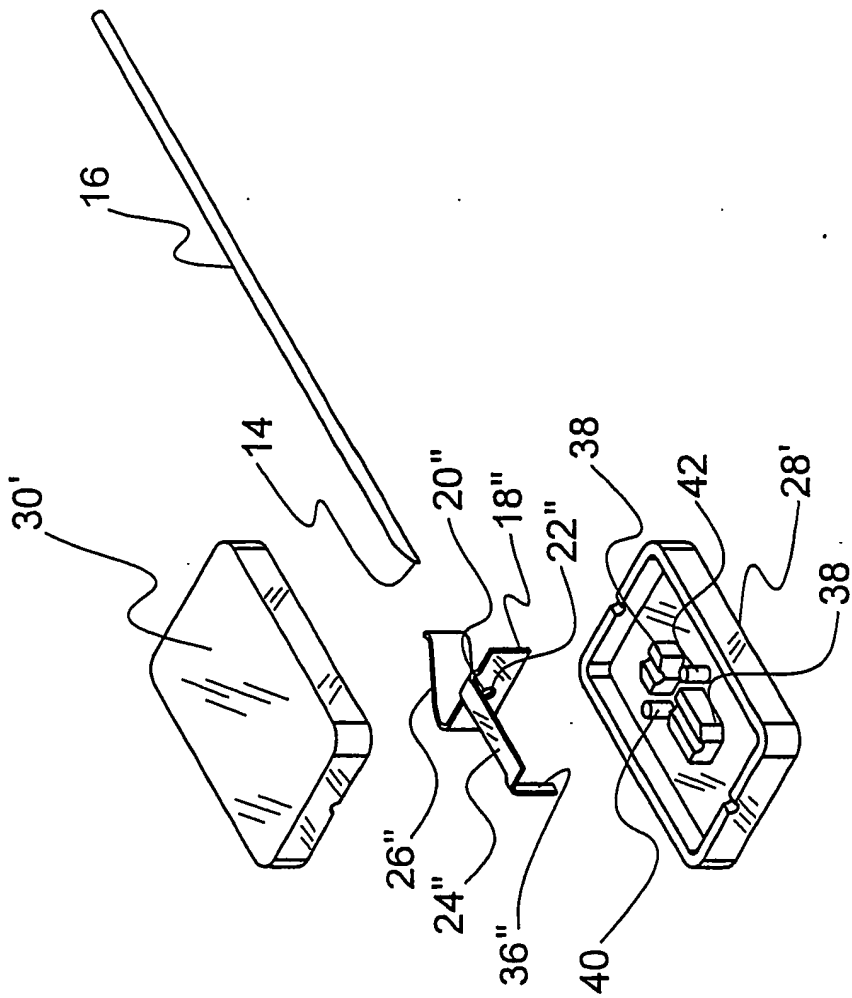


FIGURE 12

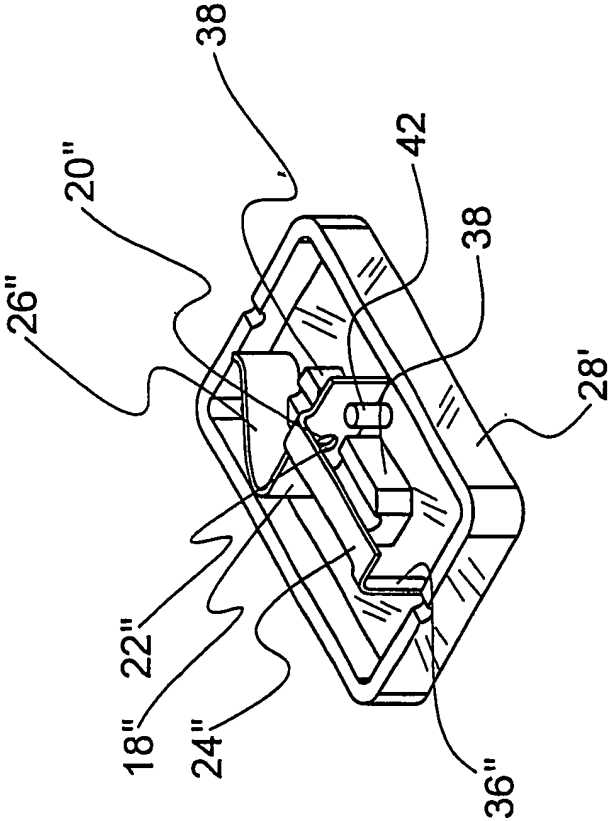


FIGURE 13

14/31

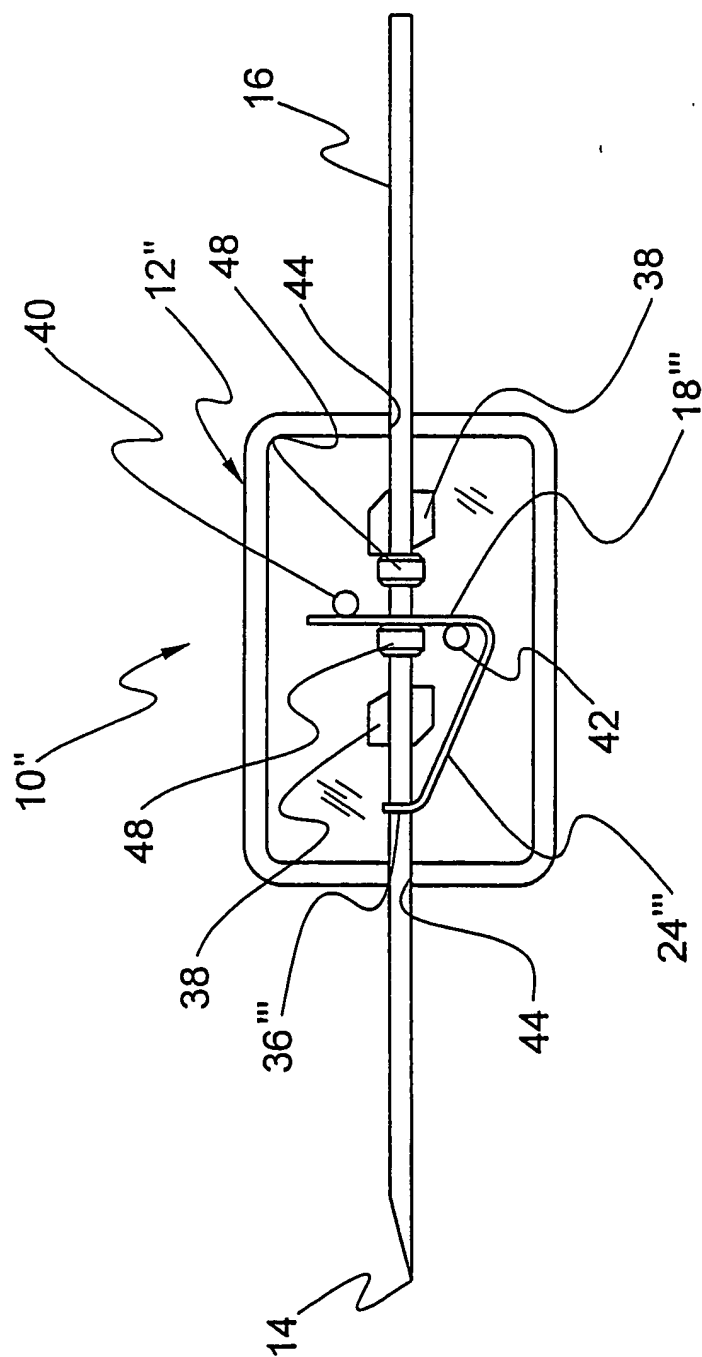


FIGURE 14

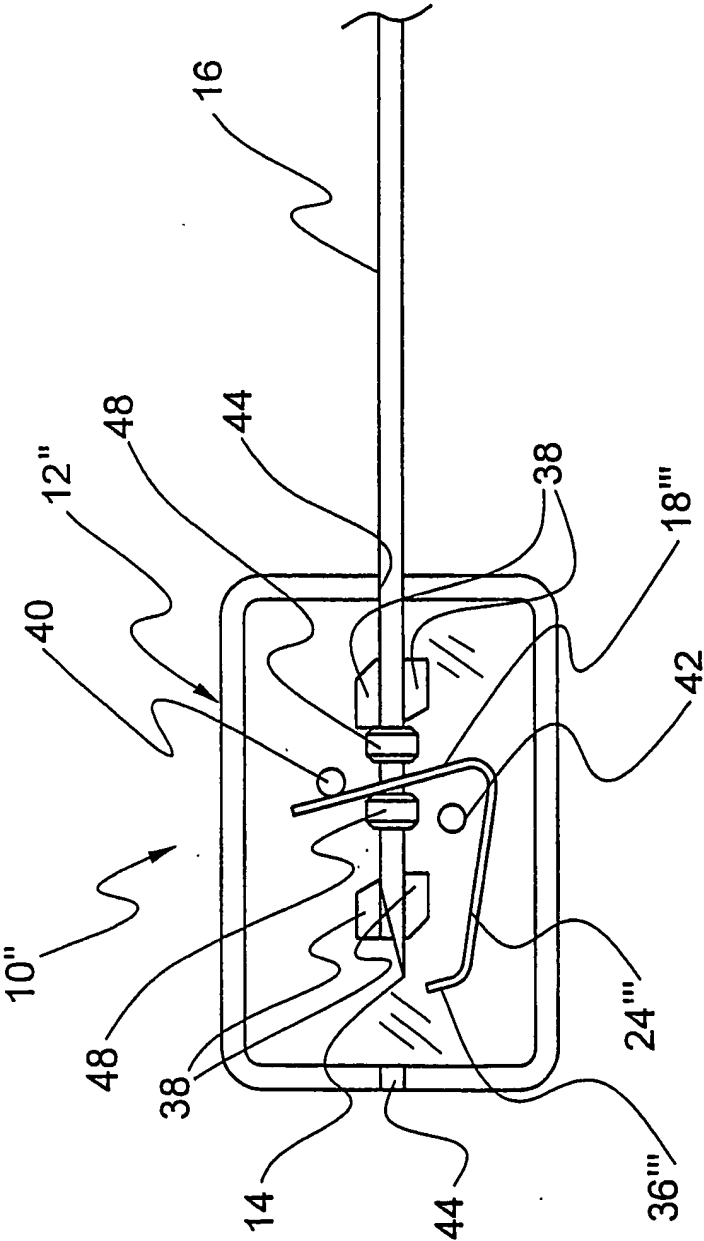


FIGURE 15

16/31

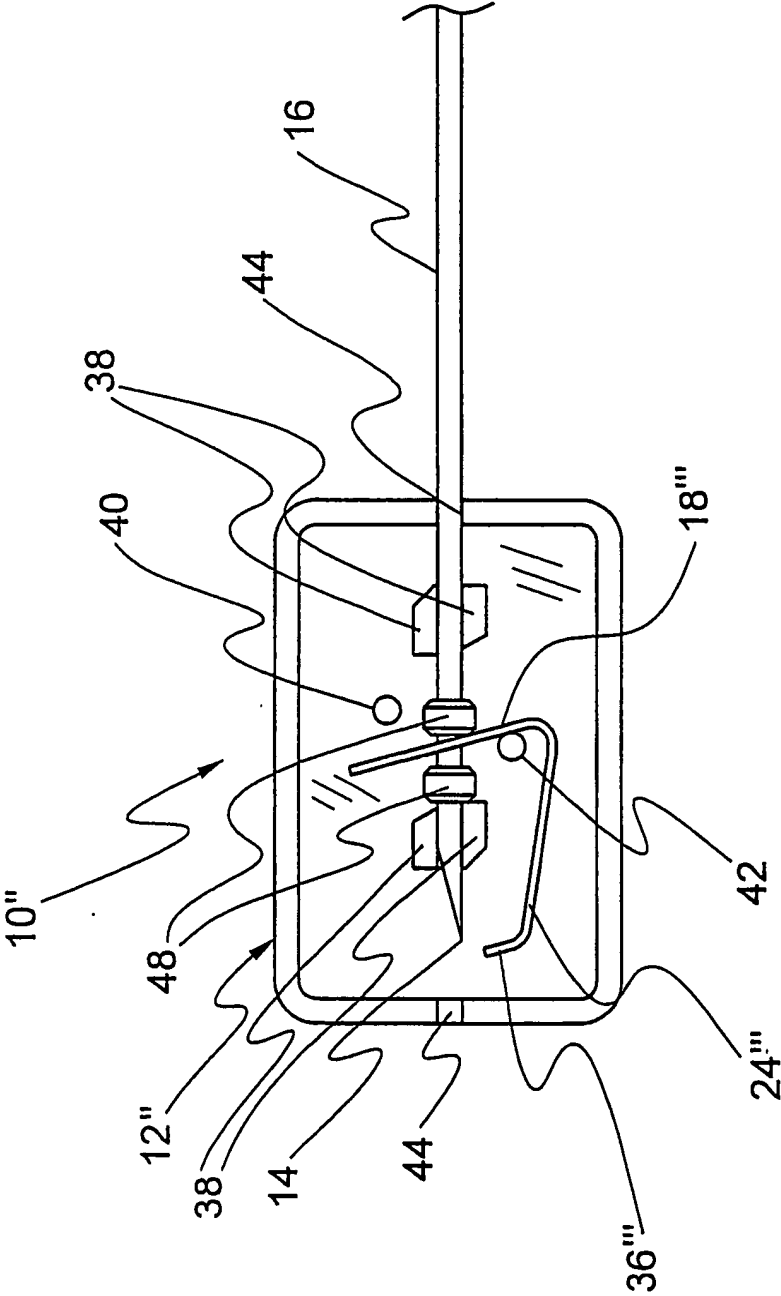


FIGURE 16

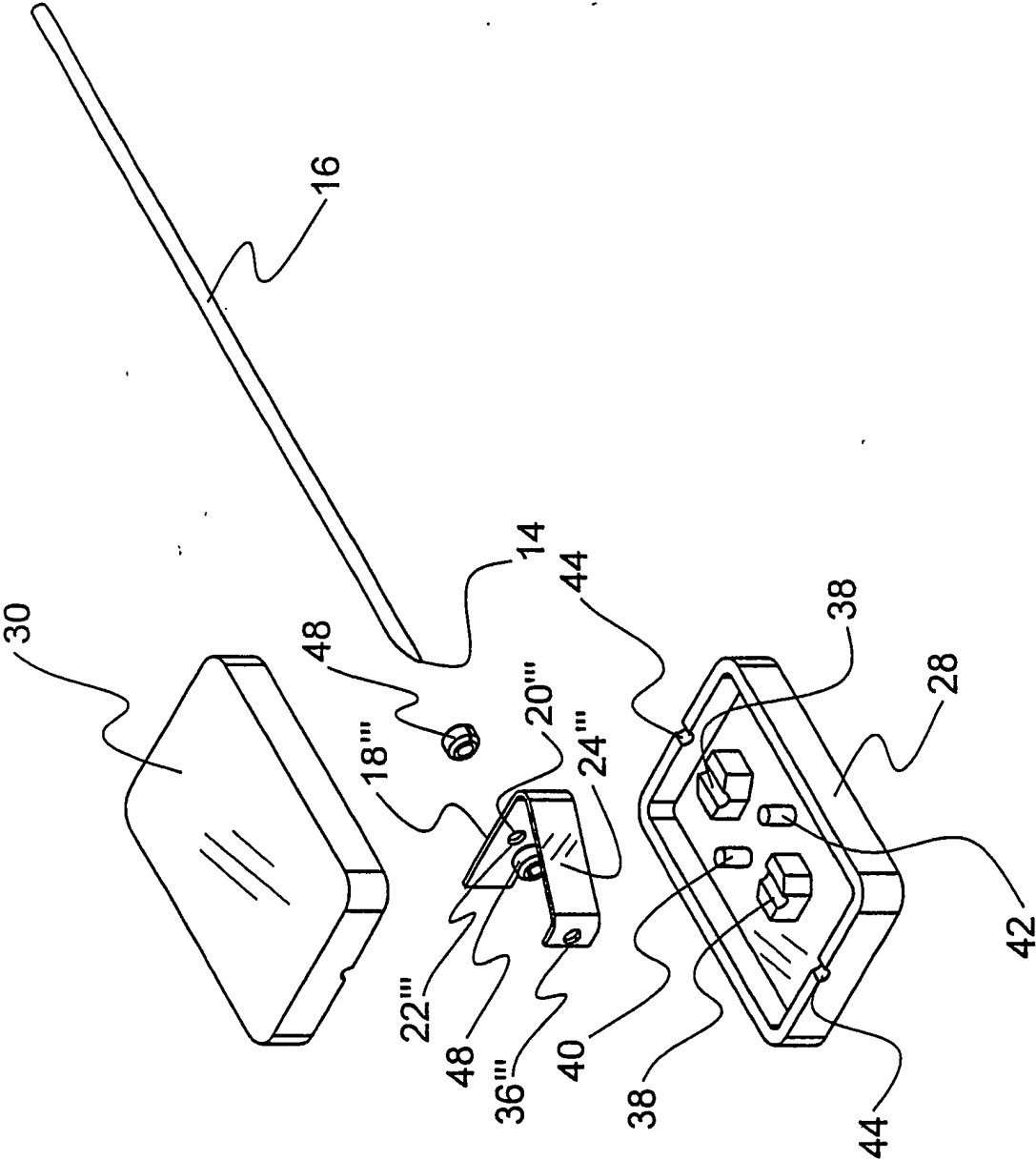


FIGURE 17

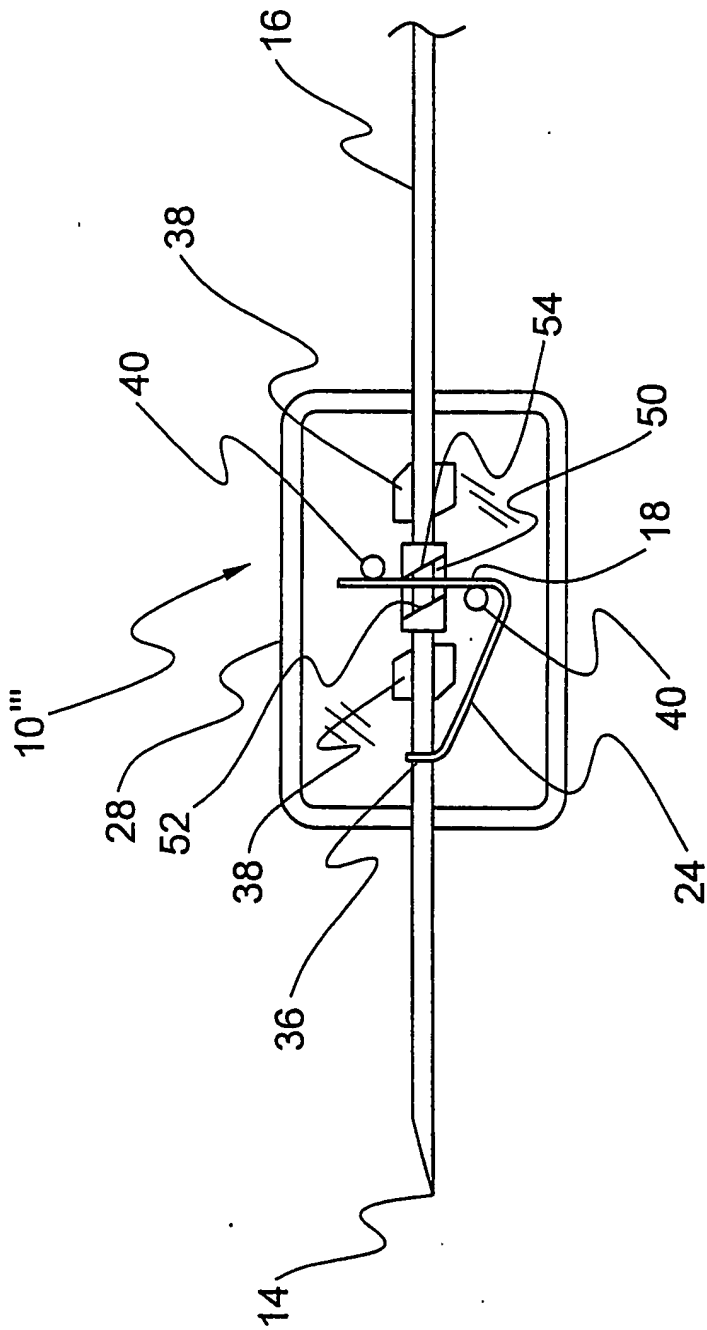


FIGURE 18

19/31

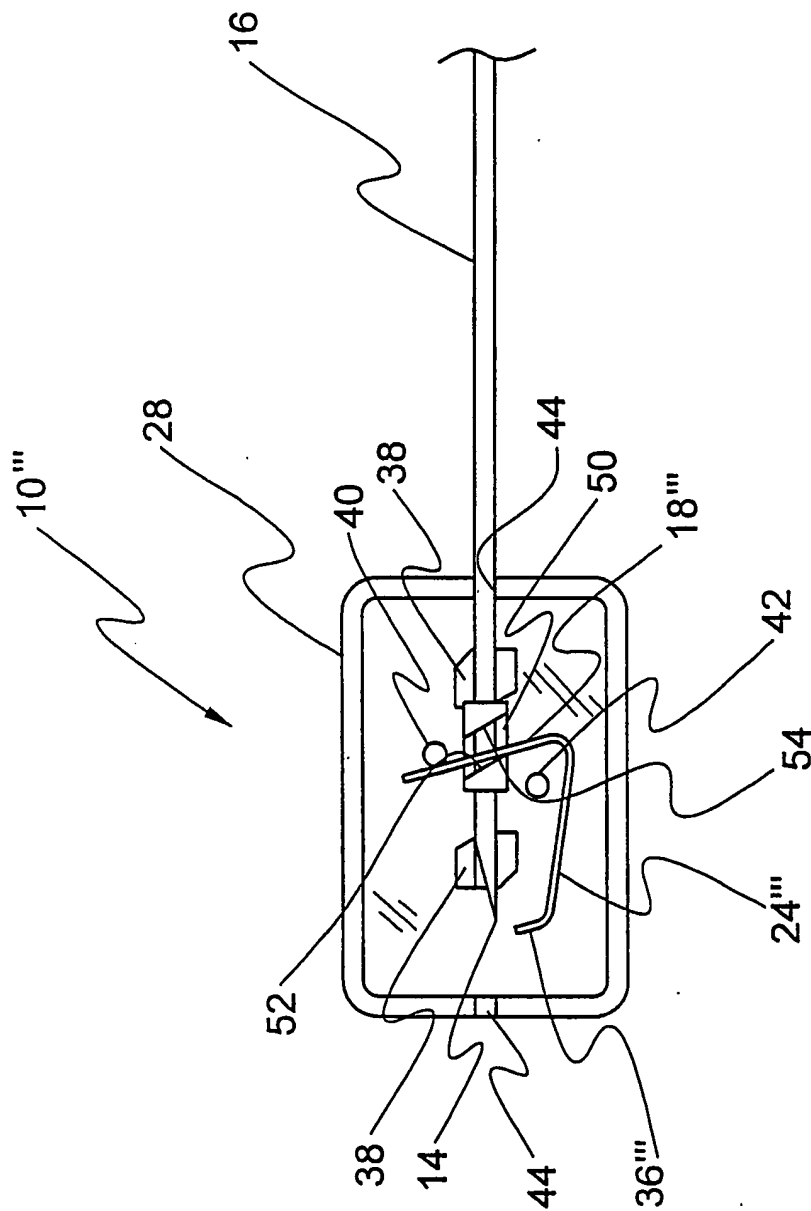
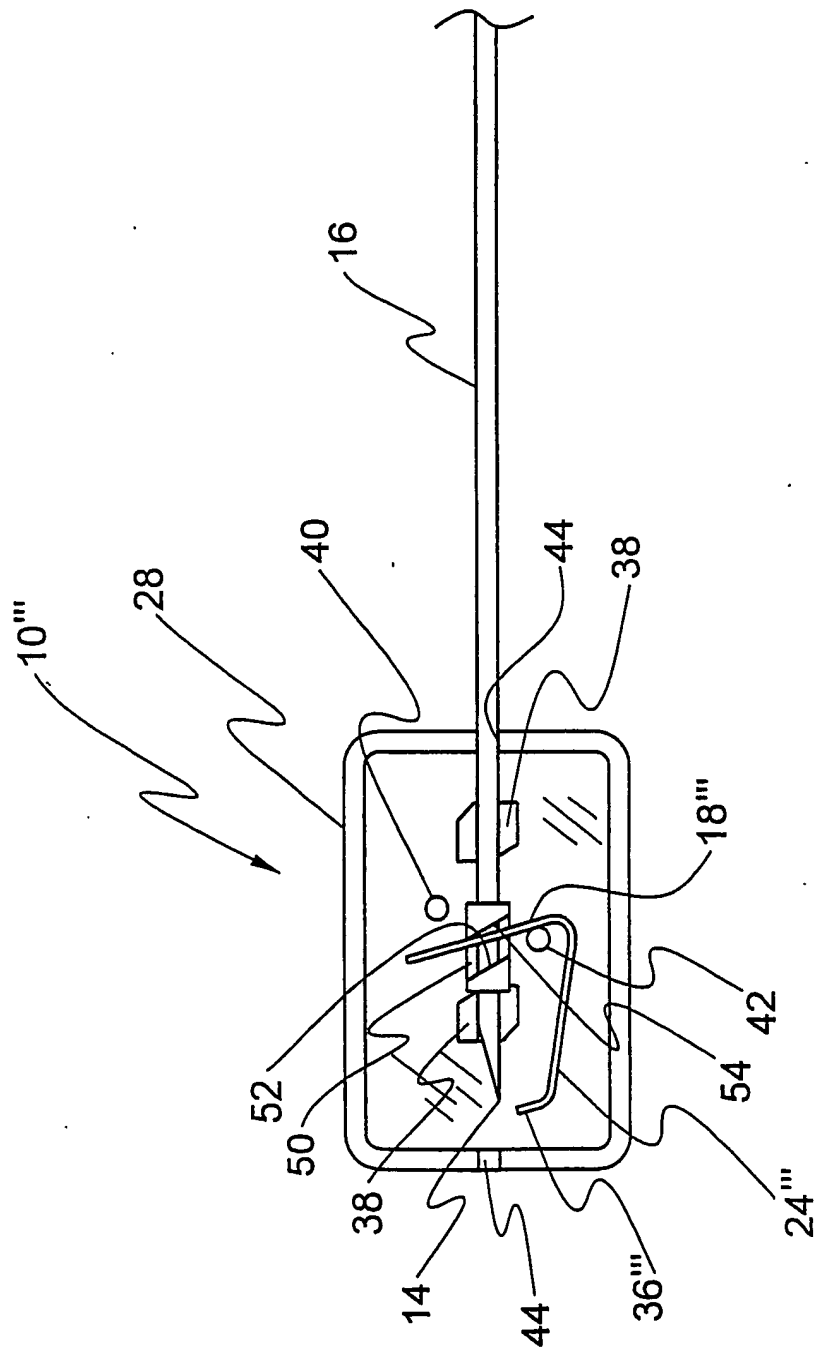


FIGURE 19



21/31

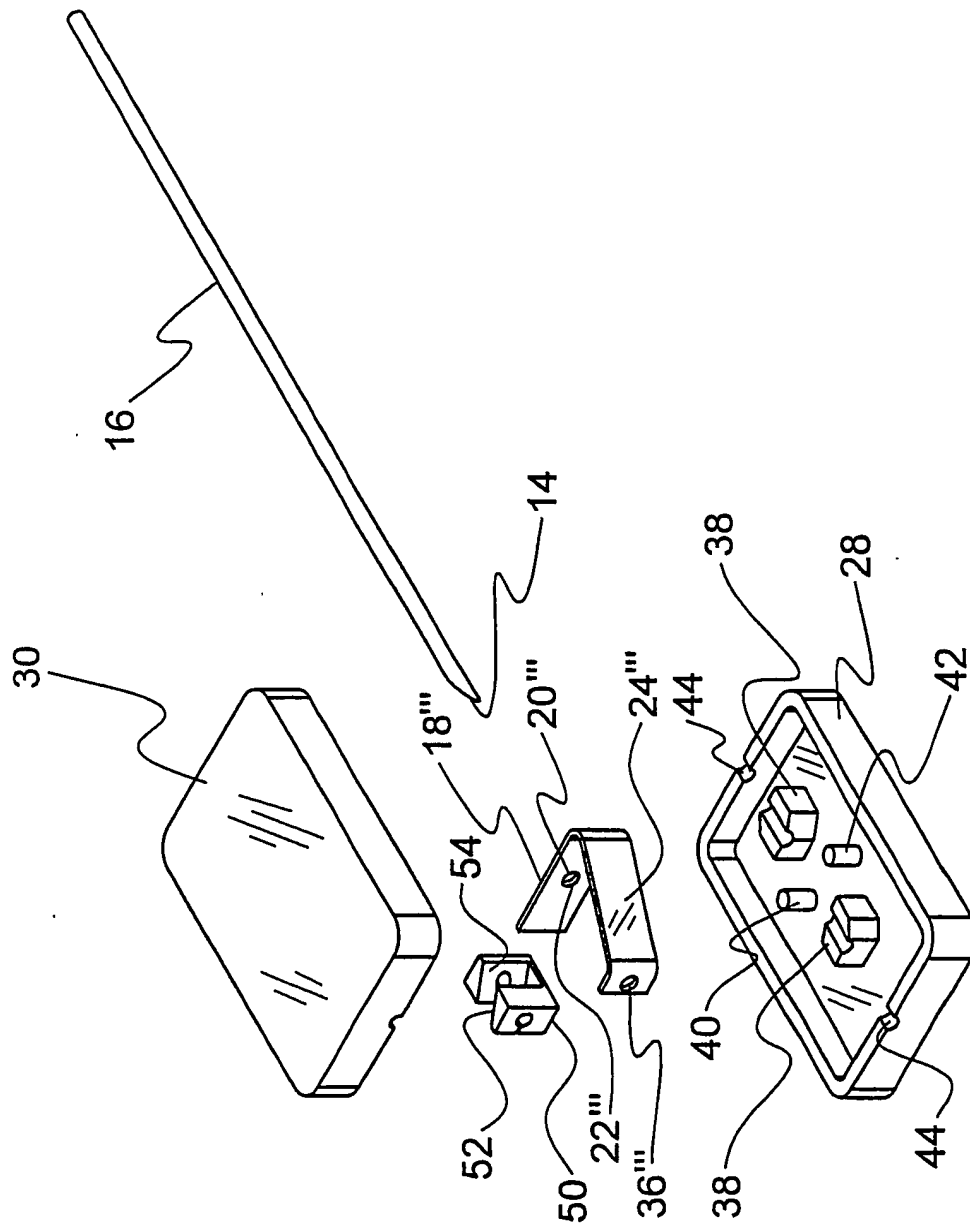


FIGURE 21A

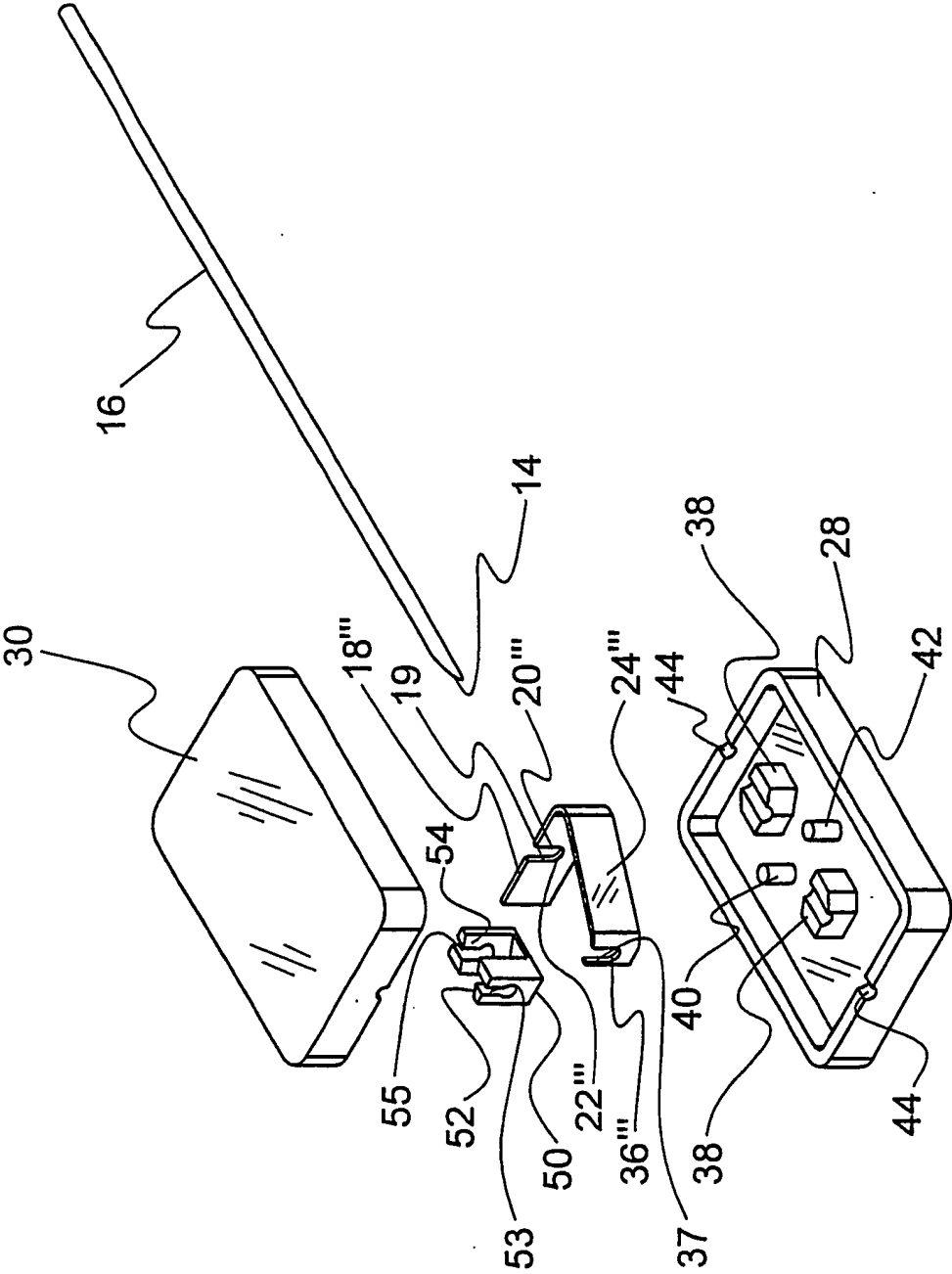


FIGURE 21B

23/31

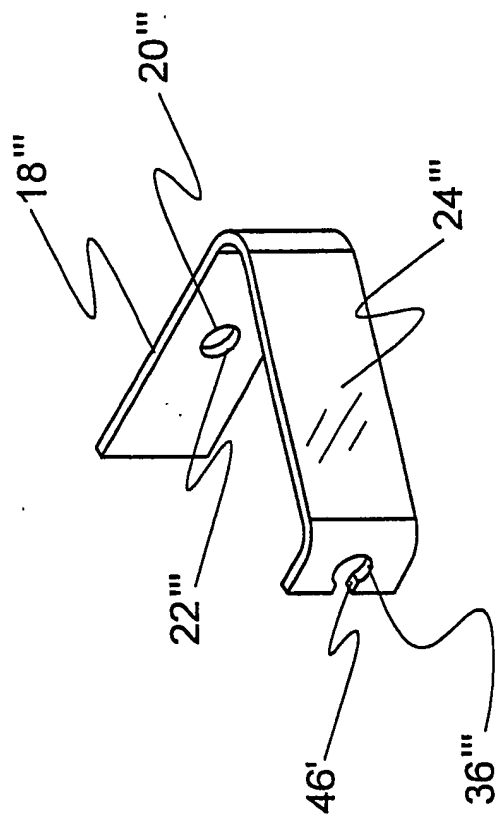


FIGURE 22

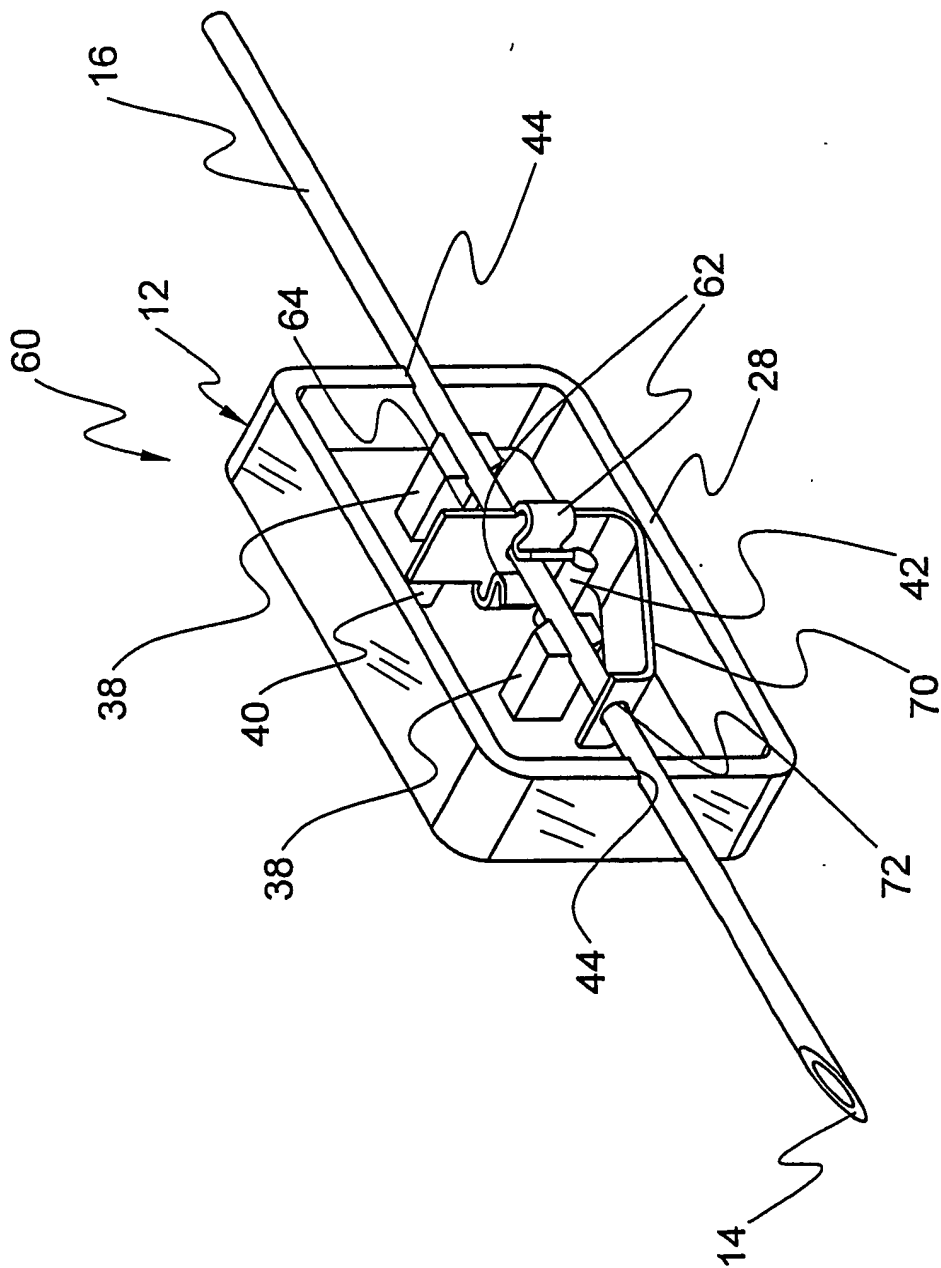


FIGURE 23

25/31

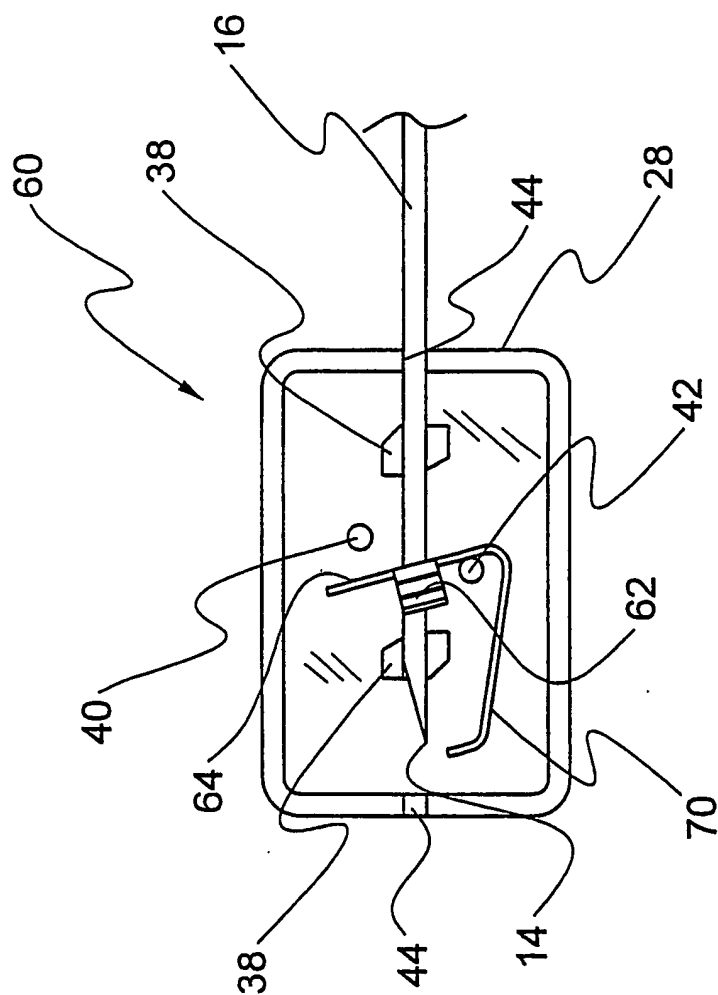


FIGURE 24

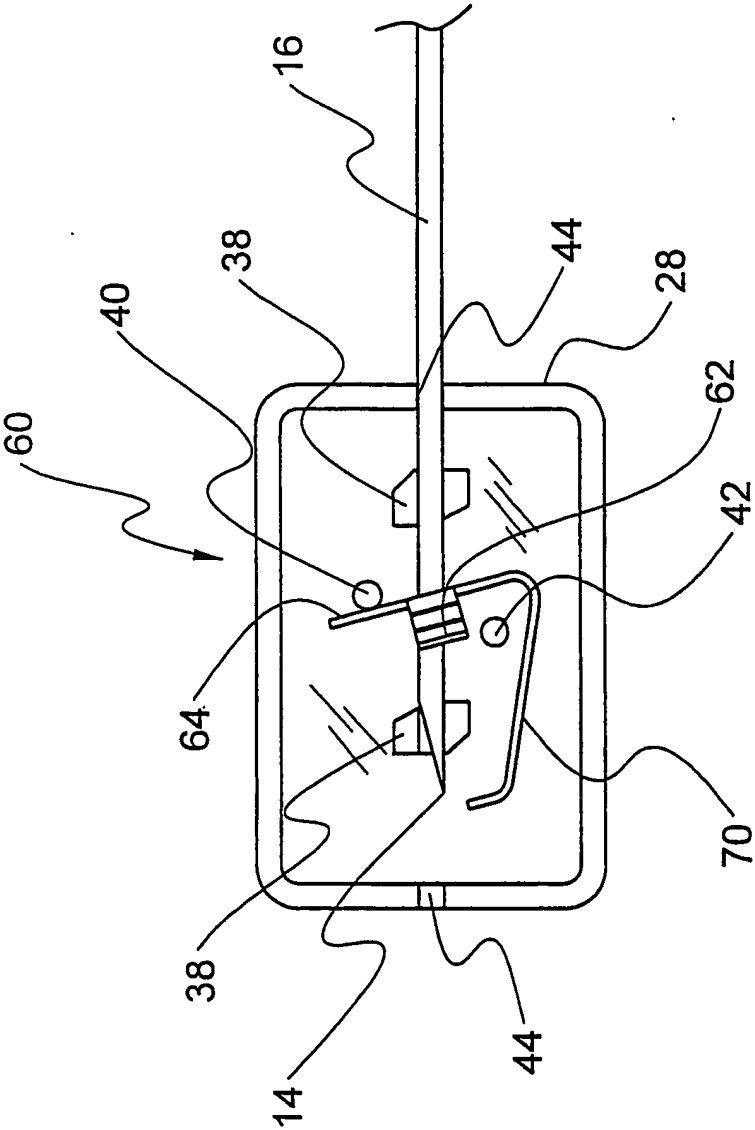


FIGURE 25

27/31

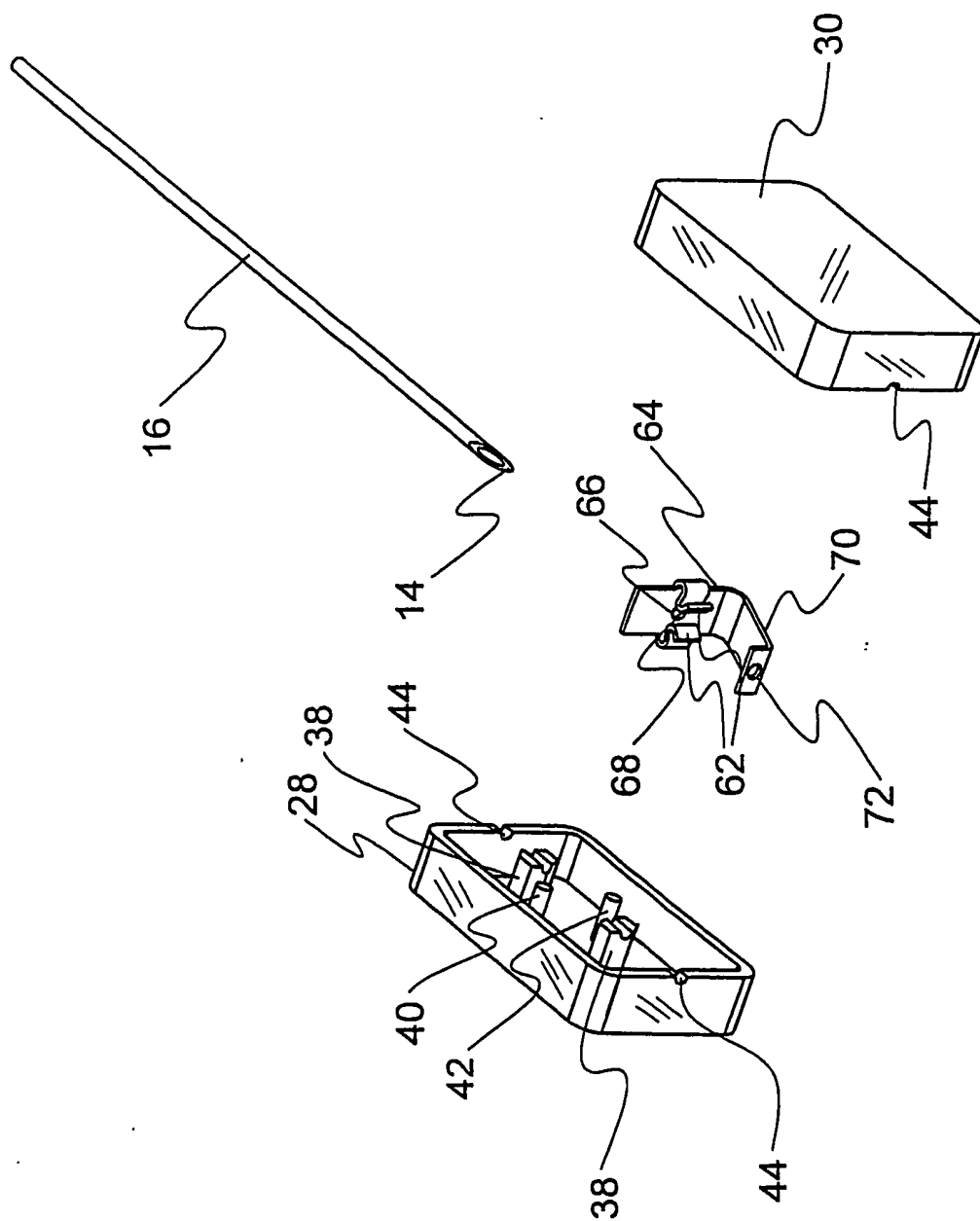


FIGURE 26

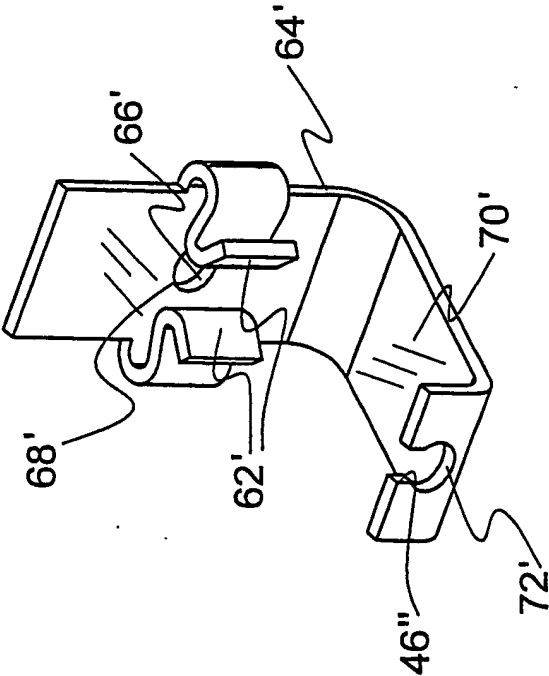


FIGURE 27

29/31

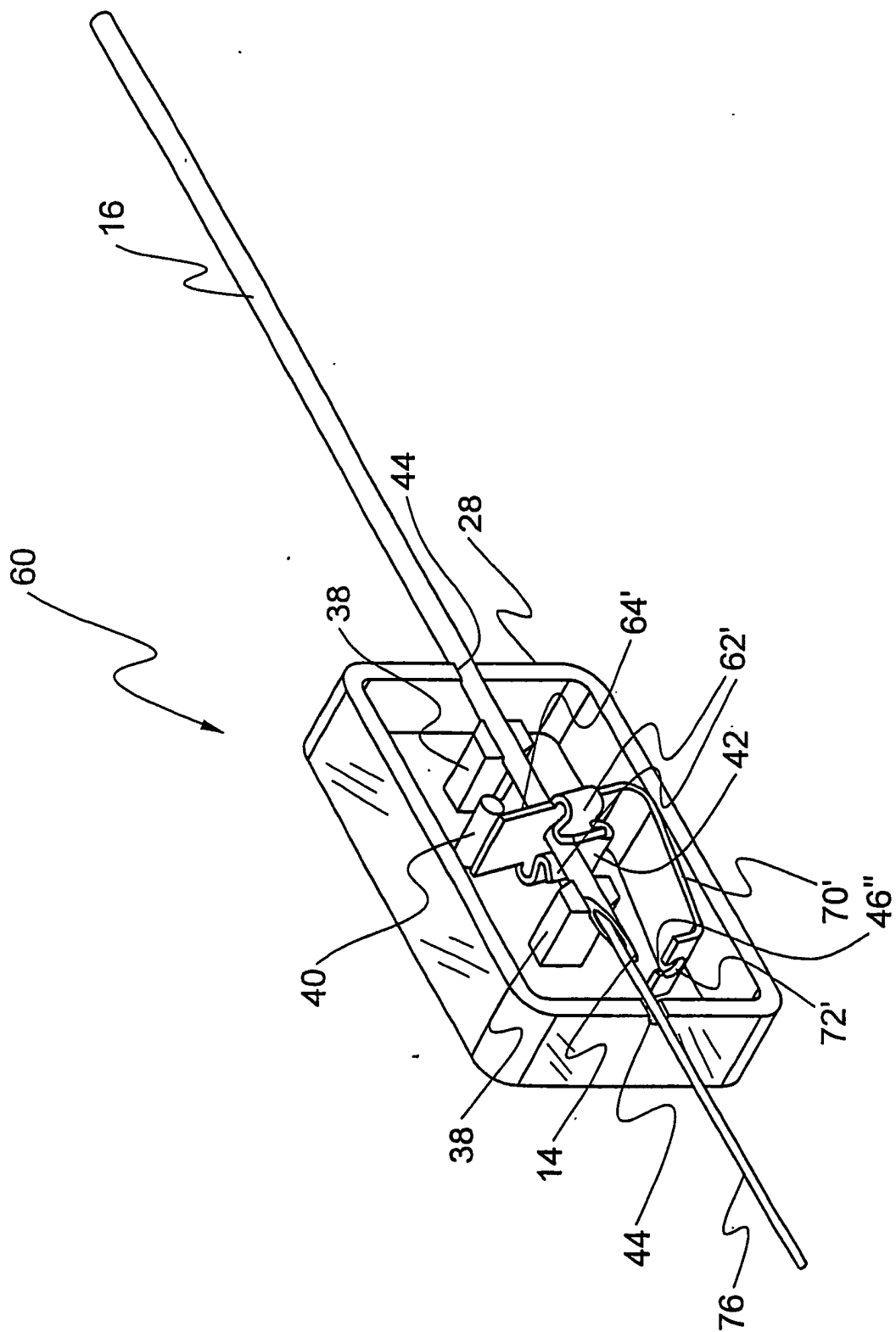


FIGURE 28

30/31

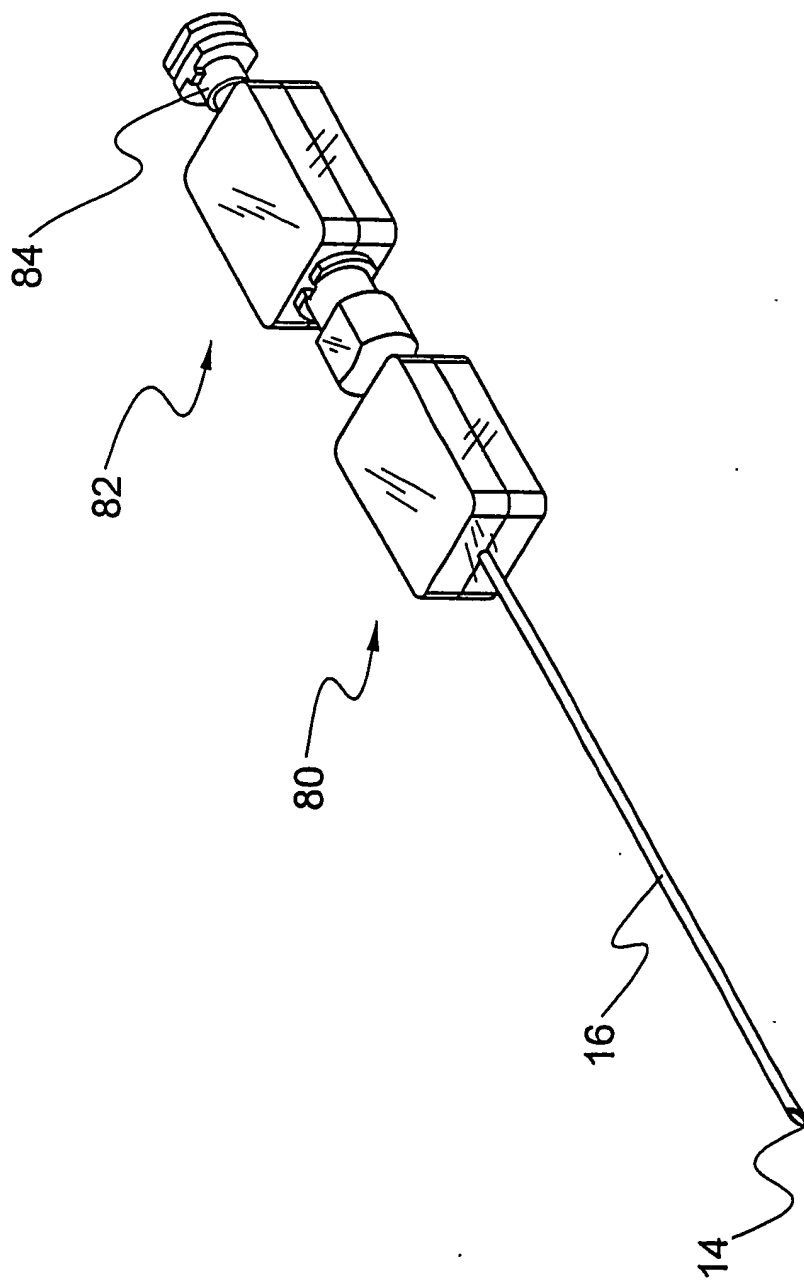


FIGURE 29

31/31

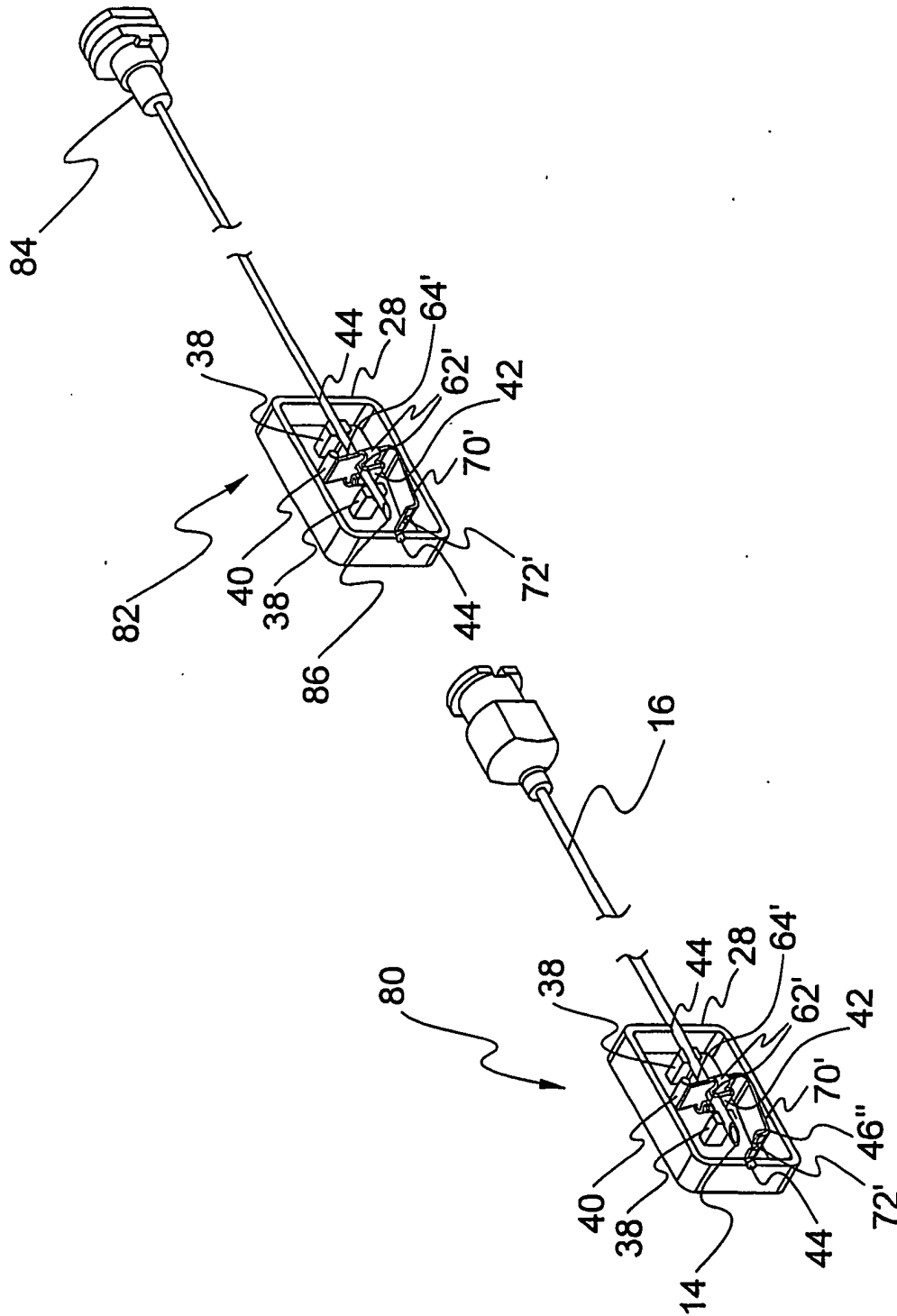


FIGURE 30

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/22093

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61M 5/00

US CL : 604/263

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/263,192,197,198,180,110,162,163,174,164.04,164.08,164.01,170.01,170.02; 128/919

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EAST (clip)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,328,482 A (SIRCOM et al) 12 July 1994, see figures 35 and 52	1,2,4-6,12,14,21

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

09 October 2003 (09.10.2003)

Date of mailing of the international search report

25 NOV 2003
Authorized Officer

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Cris L. Rodriguez

Telephone No. (703) 308-2194

Facsimile No. (703)305-3230